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The Reliability and Validity of a Simulated Airway Model that Quantifies Physical Forces Exerted During Endotracheal Intubation in a Clinically Demanding Scenario

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The Reliability and Validity of a Simulated Airway Model that Quantifies Physical Forces Exerted During Endotracheal Intubation in a Clinically Demanding Scenario.

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in at Virginia Commonwealth University.

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TABLE OF CONTENTS

Page

Page

Page

Page

LIST OF TABLES

Page

LIST OF FIGURES

Page

ABSTRACT

THE RELIABILITY AND VALIDITY OF A SIMULATED MODEL THAT QUANTIFIES PHYSICAL FORCES EXERTED DURING ENDOTRACHEAL INTUBATION IN A CLINICALLY DEMANDING SCENARIO

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Health Related Sciences at Virginia Commonwealth University.

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The main purpose of this research was the development of an experimental model that allows for the assessment of pressure and thereby, the forces associated with interventions related to airway management. The foundation of this research was to develop, and assess the validity and reliability, of a method of quantifying the force experienced by a patient during airway management.

Following IRB approval and the development of a unique simulation model that employs transducers situated in key anatomical locations to determine forces, a multivariate profile analysis with covariate of experience using a MANCOVA approach was conducted. The statistical design consisted of 102 subjects testing the dependent measure of pressure for the following techniques: Fiberoptic intubation, the Fastrach™ LMA, the # 3 C-Mac video laryngoscope, and the Trachlight®. Independent variables

analyzed were practitioner types: emergency medicine physicians, certified registered nurse anesthetists, and anesthesiologists, all tested over five locations: Chicago, Las Vegas, Atlanta, Seattle, and Boston, with a co-variable of experience.

Analysis demonstrated no difference in force attributed to the location, the airway provider or their interactions. This was contrasted by the finding that 81% of the variance in pressure scores was due to differences in airway techniques. The mannequin was also able to discern a subpopulation within techniques which lends to its validity. The mannequin preformed consistently regarding reproducible findings following the setup and dismantling over time and locations. This would seem to begin to form the bases of a valid and reliable tool for this and future research.

CHAPTER ONE

In the United States healthcare system, when definitive airway management is deemed necessary, any one of several practitioner types using one of a variety of techniques will be called upon to manage this task. The paramount significance and ramifications of airway management for the critically ill are well recognized by the medical community. Three groups with particular interest in airway management are the American Association of Nurse Anesthetists (AANA), the American Society of Anesthesiologists (ASA), and the American College of Emergency Physicians (ACEP). Given the interest by such organizations, and the life and death ramifications of airway management, one would think that an evidence-based process would drive this intervention; surprisingly this is not always the case. Although much research has been conducted relative to the many facets of routine and difficult airway management, gaps continue to exist within the literature. One such gap relates to the mechanical forces experienced by the patient during interventional airway management. The main purpose of the current research is to provide a means to fill this gap and allow for the comparison of devices, providers, and their interplay in a meaningful way.

Airway Management

Intubation

The significance of airway management can perhaps be recognized best by the realization that, once control of the airway is lost, a patient's survivability is measured in minutes. Among many clinician-researchers, Peterson and colleagues (Peterson et al., 2005) pointed out that difficulty managing the airway is often associated with significant adverse respiratory events. For the purposes of the current research study, advanced airway management will reference what is commonly referred to as oraltracheal intubation. First described by Ibn Sina in 1025 in his works, Canons of Medicine, intubation now consists of the placement of a specially designed tube (endotracheal tube, ETT) into the patient's trachea for the purpose of establishing and maintaining an airway. This tube can be used to facilitate the ventilation and respirations of the critically ill and is recognized as a lifesaving technique. For orotracheal intubation to be successful, the visualization of the glottic inlet either by direct or indirect means is established. Inadequate visualization, and thus difficulty or the inability to place an ETT properly can result in a spectrum of undesirable outcomes. This spectrum ranges from the inability to secure the airway, resulting in the increased risk of aspiration of gastric contents, on to and including the complete failed airway resulting in death.

Difficult Intubation

The relationship between difficult tube placement and poor glottic view is well established. This has resulted in the adoption of a formal grading system for the description of glottic views attributed to Cormack and Lehane (Cormack & Lehane,

1984). Also established is the relationship between glottic view degradation during intubation attempts and the use of spinal immobilization (Hastings & Wood, 1994). This concept was then further explored and defined by Santoni et al. in 2009. By instrumenting a Macintosh 3 blade, Santoni and colleagues demonstrated that at least twice the amount of force was required to intubate, and therefore achieve an acceptable view of the glottic opening, in the same patient when spinal immobilization was applied. This degrading of the obtained view of the glottic opening associated with laryngoscopy is true to the extent that Kihara and colleagues (Kihara, Yaguchi, Taguchi, Brimacombe & Watanabe 2005) suggested, and used, spinal immobilization to simulate the management of difficult airway situations during intubation. By applying this to a mannequin, the simulation of the difficult intubation scenario can be standardized and easily replicated.

Force and Intubation Research

With the exception of blind techniques, all endotracheal tube placements require the visualization of the glottic inlet either by direct or indirect means. Force, is to a greater or lesser extent, applied to achieve adequate visualization of the glottic opening. This visualization is achieved by manipulating the patient's head and or airway structures during one method or another of intubation. Interest in the physical forces exerted during the intubation process is not a new one. Past attempts at quantification of forces has centered on direct laryngoscopy using Miller, and later, the Macintosh laryngoscope blades. This led researchers to explore the forces of intubation by the means of modifications made to the standard laryngoscope handles. Although several researchers

were successful with this method, it could not be applied to other means of intubation and interest ended there. This has resulted in the application of research regarding forces conducted thus far being complicated by things such as, insufficient statistical power, lack of the ability to generalize research findings, introduction of new techniques and tools, as well as the added complications associated with a temporal components of research.

The many contemporary tools and techniques developed to facilitate intubation demonstrate the continued relevance of this topic. Advancement of the domain of airway management by the introduction of new methods has been in direct response to difficult situations encountered by clinicians. Further relevance has been demonstrated in the literature by several researchers attempting to quantify spinal movement, the result of force, applied during the intubation process. For this, most have chosen to use radiological methods on healthy intact volunteers or developed spinal injured cadaver models. These techniques have introduced additional variability and have lacked a unified method or approach that would allow cross comparisons. The introduction of new tools has led to the lack of relative comparative analysis of devices both new and old. All of this has resulted in an incomplete and changing knowledge foundation. From this incomplete knowledge base, clinicians are called upon to make evidence driven decisions on which to base their practice. Past efforts to compare devices have also been complicated by the subjective nature of the measurements used. Most have chosen a measurement such as the Cormack grading of view (Cormack & Lehane, 1984) or an intubation difficulty-rating scale used by some.

In an effort to control for some of the variability seen, a standardized simulated patient model was developed for this study. The use of an objective and standardized instrumented mannequin as an assessment tool will allow for the comparison of several techniques and devices.

Purpose of Research

The purpose of this study was to develop and establish the initial reliability and validity of an airway-training model. This model will allow for a quantitative analysis of the forces that would be expected to occur in a patient undergoing a wide realm of definitive airway management techniques and thus allow for the remedy of many of the shortcomings in the literature. Under controlled, simulated conditions, a comparison was made of the forces applied during the placement of an endotracheal tube using a variety of approaches. This was achieved by using a modified patient simulator. A Laerdal Adult Airway Trainer Intubation Mannequin (Figure 1, Laerdal Airway Management Trainer, Laerdal, Stavanger, Norway) was carefully modified with the addition of three fluid-filled compartments. Each compartment was capable of pressure transduction and recording when connected to an electronic monitor. Once modified, the mannequin was capable of providing quantitative measures of physical force as feedback. The Laerdal Airway Management Trainer Mannequin has been used for teaching advanced airway management and is prevalent throughout the airway management literature. The mannequin is considered to have a high degree of face validity for airway training in both the anesthesia and the emergency medicine communities.

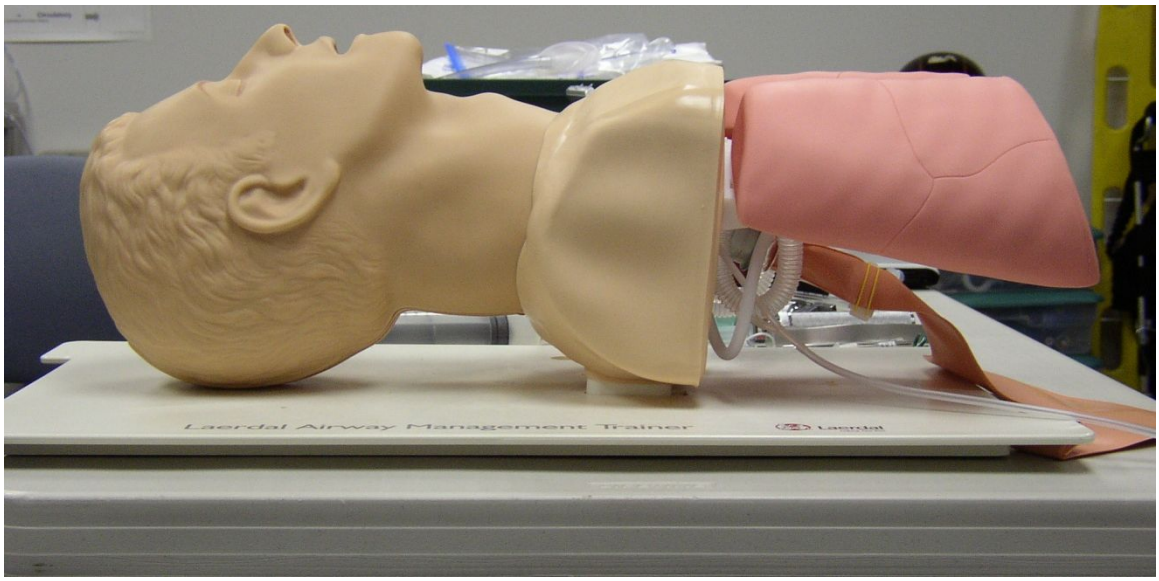


Figure 1. Laerdal Airway Management Trainer

Schematic representations of both phase one and the main study can be found below. For phase one (See Figure 2), subjects were assigned by using a random number generator set between zero and two. Subjects who generated a number form 0-1 entered the diagram from the left. Subjects who generated a number grater then one entered the diagram from the right.

	X_1		X_2	
→	$(O_1\text{-}O_2)$	>	$(O_1\text{-}O_2\text{-}O_3)$	
	$(O_1\text{-}O_2)$	<	$(O_1\text{-}O_2\text{-}O_3)$	←

X1 = Unaltered Laerdal Mannequin
X2 = Altered Laerdal Mannequin
O1 = Self assessment of force made by subject
O2 = Assessment of force made by observer
O3 = Maximum force recorded by sensors within mannequin

Figure 2 Schematic Representation of Phase One

For the main study, the basic plan was repeated at each of the five locations (L_1-L_5) (See Figure 3). Thirty subjects, ten from each of the three subject-types (S_1-S_3), was

L_1		X_1	X_2	X_3	X_4	X_5	X_6
	S_1 (1-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_2 (1-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_3 (1-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
L_2		X_1	X_2	X_3	X_4	X_5	X_6
	S_1 (11-20)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_2 (11-20)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_3 (11-20)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
L_3		X_1	X_2	X_3	X_4	X_5	X_6
	S_1 (21-30)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_2 (21-30)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_3 (21-30)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
L_4		X_1	X_2	X_3	X_4	X_5	X_6
	S_1 (31-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_2 (31-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_3 (31-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
L_5		X_1	X_2	X_3	X_4	X_5	X_6
	S_1 (41-50)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_2 (41-50)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_3 (41-50)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)

X1 = Trachlight®
X2 = C-Mac 3 video laryngoscope
X3 = Flexible fiberoptic bronchoscope
X4 = Standard laryngoscopy using a # 3 Miller blade
X5 = Fastrach™ LMA
X6 = Standard laryngoscopy using a #3 Macintosh blade

O1 = Maximum force recorded by mannequin sensors
O2 = Time taken to place ETT

S1 = Emergency medicine physicians (MDEMs)
S2 = Certified registered nurse anesthetist(CRNA)
S3 = Anesthesiologists (MDAs)

L1 = Chicago Ill.
L2 = Las Vegas NV.
L3 = Atlanta GA
L4 = Seattle WA
L5 = Boston MA.

Figure 3. Schematic Representation of Main Study

the enrollment goal at each location. Each subject performed six intubations, representing the six differing techniques (X_1-X_6) included in this study. For each intubation, the

maximum force recorded by the mannequin sensors as well as the time taken to place the ETT was recorded. Also gathered from each subject was:

1. Type of provider
2. Length of time practicing
3. Course day that data was obtained.

This project will further allow researchers to evaluate the interplay between the type of medical provider engaging in an interventional airway maneuver, and the choice of intubation technique selected. This interplay has universal application to all definitive airway management in that once undertaken, force experienced by a patient and the time required for ETT placement is a common interest for all scenarios. The time required to secure ETT placement is significant in that timely airway management reduces patient risk for aspiration and hypoxia. Therefore, relative time is of interest in all airway management research. If an endotracheal tube placement technique allows for minimal force but has a relatively long time requirement, it is of little benefit to the patient. The use of the modified model allows for the study of the relative contribution of different types of medical providers, three in the case of this research, on the force used for ETT placement. For this reason, all subjects within the three provider types used each of the selected devices that are representative of the current practice of advanced airway management.

Significance of Research

The significance of this research lies in its applicability to the type of airway management that occurs each day, throughout the world, in thousands of hospitals

providing care to the critically injured. This standard simulation patient model represents a patient who is spinal immobilized. This choice was made due to the known relationship between glottic view degradation during intubation attempts and the use of spinal immobilization (Hastings & Wood, 1994. Santoni et al., 2009). This ability to simulate difficulty in intubation was married with the known relationship of spinal immobilization and glottic exposure degradation. Kihara, Yaguchi, Taguchi, Brimacombe and Watanabe (2005) used this type of simulation in their study. The degradation of the view of the glottic anatomy during intubation attempts in healthy volunteers was achieved through the application of in-line spinal stabilization. The model for this study was chosen in order to demonstrate applicability to spinal immobilized patients, although controlling the degree of force experienced by any patient is a universally worthwhile goal.

Other beneficial outcomes of this research are the potential to employ actively the model developed during this study to the teaching setting, as well as to empower future airway research and testing by making available a virtual instrument that provides quantitative feedback. The nature of the real-time, quantitative feedback may prove invaluable in the future training of healthcare students, as well as the on going, continuing education of licensed providers. This model will also allow for the future testing of newly developed tools and techniques, while at the same time allowing for meaningful cross comparison to existing methods.

CHAPTER TWO

The primary purpose of this study is to provide a reliable and valid methodology for evaluating the performance of airway devices, airway care providers, and their interplay in a systematic way. How these variables relate to the mechanical forces experienced by a simulated patient during interventional airway management will be elucidated.

Although much research has been conducted relative to the many facets of routine and difficult airway management, gaps exist within the literature. In the following chapters, several of the overlapping topics relative to this subject will be explored. These topics are:

1. History of Intubation
2. Airway Research
3. Type of Provider and Airway Management
4. Incidence of Spinal Injury and Associated Secondary Neurological Injury
5. Head and Associated Spinal Movement During Airway Management
6. Head and Spine Immobilization
7. Spinal Immobilization and its Effect on Airway Management
8. Use of Simulation-Models in Past Airway Research
9. Measurement of Force in Past Airway Research

10. Past Comparison of Technique and Devices for Airway Management

History of Intubation

The Muslim scholar Ibn Sina was the first to describe intubation in 1025 in his works, Qanun or the Canons of Medicine. These techniques evolved over time into either the surgical approach of inserting a tracheal tube or as described by William McEwen in 1880 in his work entitled; "Clinical observations on the introduction of tracheal tubes by the mouth instead of performing tracheotomy orlaryngotomy" the blind oral approach (McEwen, W., 1880). It was not until 1895 when Alfred Kirstein was able to document the first direct visualization of the human larynx (Kirstein, 1895). This feat was accomplished using a device originally designed to inspect a patient's esophagus. Up to this point in time, it was believed that direct visualization of the larynx and glottic opening was impossible due to the anatomical curvature of the human anatomy. Kirstein then worked to modify this device eventually resulting in what now could be recognized as the first laryngoscope. Chevalier Jackson (1913) described modifications to the developing laryngoscope blade and techniques specifically for tracheal tube placement. Nearly 30 years later, Robert Miller (1941) described what is known today as the Miller blade for direct laryngoscopy. Two years later, Robert Macintosh (1943) introduced the Macintosh blade. According to Macintosh, this blade was introduced in order to lessen the difficulty of exposing the larynx that was normally encountered while performing direct laryngoscopy with the long straight Miller blade (Macintosh, 1943).

Since the introduction of these two laryngoscopy blades, many modifications, techniques, and devices have been put into practice. Interestingly, even with the passing

of nearly seventy years, these two laryngoscopy blades and their associated techniques are still the most commonly used devices to achieve intubation throughout the world. With the recognition of these two techniques as the preferred method of intubation, they are the gold standard to which other intubation techniques are compared. How these techniques relate to the mechanical forces experienced by the patient during intubation and how they compare to other techniques during airway interventions was explored here using a new model for quantifying such forces.

Airway Research

Caplan, Posner, Ward and Cheney (1990) reported that 34% of adverse outcomes reported to the American Society of Anesthesiologists (ASA) closed claims project were associated with respiratory events. Of these claims, 35% were attributable to esophageal intubation and/or difficult intubation. Larson and Jordan (2001) found a similar rate of 38% in their analysis of Certified Registered Nurse Anesthetists (CRNA) closed claims for respiratory incidence for the years 1987-1996 (Larson & Jordan,. 2001). These findings helped to spark interest in difficult airway management ultimately resulting in the publication of such documents as “Practice Guidelines for Management of the Difficult Airway” (American Society of Anesthesiologists Task Force on Difficult Airway Management, 1993). This document was then updated in 2003 with several changes in the hopes of reflecting the changing nature of airway management (American Society of Anesthesiologists Task Force on Difficult Airway Management, 2003). Documents such as these proved to be a focus point for airway care providers in that they

called for evidence-based development of airway management techniques in the face of what was up to this point, an anecdotal-based practice.

Research in the field of airway management has suffered from a number of difficulties. Hung and Law described these difficulties in 2006 by stating, "Most randomized clinical trials examining airway techniques or devices involve a number of patients too small to have sufficient statistical power to draw valid conclusions …" (Hung & Law, 2006 p. 628). Further, the authors state, "almost all of the current clinical evidence in airway management consists of case reports, case series, reviews and editorials" (Hung & Law, 2006 p. 628). These authors point out that this is not unique to the study of airway management and much research is needed within the field. They call for a change in the way we think about the use of such devices as the Trachlight®, intubating laryngeal mask airways, flexible and rigid fiberoptic devices and video-assisted laryngoscopy. It is their opinion that we should no longer consider these devices as rescue devices but rather as effective primary techniques for use in both routine and difficult airway management. With this shift in paradigm, it is hoped that an increase in the use of these devices will promote mastery (Hung & Law. 2006). Additional mastery of devices and techniques other than direct laryngoscopy will allow the practitioner to match the clinical situation with the appropriate device, thus resulting in greater success with the aim of decreasing morbidity and mortality.

This was echoed by Manoach & Paladino (2007), in their review of in-line stabilization for airway management of suspected cervical spinal injured patients. They concluded that research should be conducted on alternative airway management

techniques that do not require direct visualization due to the association between spinal immobilization and difficult laryngoscopy. These authors go on to suggest that promising techniques include supraglottic devices, video-laryngoscopes and optical stylets (Manoach & Paladino, 2007).

The construction and use of the proposed model in this study should help to provide a novel approach to explore the issues put forth by Manoach and Paladino.

Type of Provider and Airway Management

Penn and Ruthman (2005) studied the involvement of CRNAs in airway management of trauma patients in a rural setting, finding that CRNAs are often the experts who are called upon to manage the patient's airway (Penn & Ruthman, 2005). Their findings help to place emphasis on airway management of spinal immobilized patients by CRNAs as a major patient population of interest for research.

Recently, Schmidt, Kumwilaisak, Bittner, George, and Hess (2008) found an association between the presence of a supervising attending anesthesiologist and a decrease in complications of emergency tracheal intubation (Schmidt et al. 2008). In an accompanying editorial, Boylan and Kavanagh (2008) discussed the issues raised by Schmidt et al. (2008) regarding competence and expertise of providers rendering emergency airway management. These findings, along with the accompanying editorial seemed to indicate that the type of provider combined with the degree of experience in rendering airway management is a very good topic for further research.

In reviewing the literature, major inconsistencies have been demonstrated regarding how the type of provider administering care is addressed. To date, a diverse

mix of subjects has been found in the growing body of literature relating to experience and airway management. Among these diverse subjects are medical students, medical residents, anesthesia residents, emergency medicine residents, attending emergency medicine physicians, attending anesthesiologists and CRNAs. This spectrum of providers introduces differences such as background, type and length of training, hands-on involvement in day-to-day practice, method of approach to problem solving and, in the case of emergency medicine, practice situations relative to patient population. In the context of so many provider types and differences, controlling for potential differences relative to the provider has been a confounding issue throughout this body of literature. It is for this reason that the type of provider has been selected as a major variable within the current study.

Incidence of Spinal Injury and Associated Secondary Neurological Injury

The epidemiologic assessment reported by Hu, Mustard and Burns (1996) for the incidence of spinal fracture in a complete population produced the parameter of 64 fractures per 100,000 persons. Their research also demonstrated a bimodal distribution with clustering occurring in young men and elderly females. They further report that 30% of those admitted with spinal fractures had their fracture located in the cervical spine (Hu et al. 1996). These findings were consistent with a study of the incidence of cervical spinal injury conducted by Hackl, Fink, Hausberger, Ulmer and Gassner (2001). In these studies, the demographics of patients who are most likely to suffer cervical spinal injury were consistent and the authors reported that one-third of all spinal injuries involve the cervical spine. Hackl's group also demonstrated an association between other injuries,

such as facial fractures, and the presence of a spinal injury (Hackl et al. 2001). Although the majority of reported injuries were found to be minor in nature, trauma to the cervical spine during care and transport can result in lifelong physical impairment and dependence. A secondary neurological injury resulting from the loss of stability of the spinal structures as a result of the initial injury can be exacerbated by manipulation during airway management. Hastings and Kelley (1993) reported a devastating secondary neurologic injury associated with airway management in a 1993 case report. This was one, if not the first case report, of its kind. It was postulated by Hastings and Kelly that the reason for the prevalent anecdotal concerns, but lacking of hard case reports in the literature regarding secondary spinal injury, was likely due to the natural hesitation of self-reporting. This case report revealed that concerns for secondary neurologic injury are not just theoretical but have been reported (Hastings & Kelley 1993). The need to stabilize manually a patient's spine during airway management imposes similar conditions as those found during difficult airway management of patients independent of spinal immobilization. This commonality of intubating conditions allows for the re-creation of difficult intubation conditions with the application of spinal immobilization. This commonality also allows for application of information across the two populations of spinal immobilized patients and those found to be difficult to intubate.

Head and Associated Spinal Movement during Airway Management

Horton, Fahy and Charters (1989) demonstrated that extension at the craniocervical junction was near maximum during x-ray laryngoscopy using a Macintosh blade without immobilization. Aprahamian, Thompson, Finger and Darin (1984)

demonstrated that in a cadaver model, the act of airway management did produce significant movement of a surgically inflicted C5-C6 spinal injury. According to the authors, this movement appeared to be only minimally mitigated by standard spinal immobilization techniques (Aprahamian et al. 1984). In 1986 Majernick, Bieniek, Houston and Hughes reported finding that there was a significant decrease in the movement of the cervical spine when in-line stabilization was applied (Majernick et al. 1986). The apparent differing views regarding the utility of spinal immobilization has continued and has yet to be resolved.

Sawin et al (1996) conducted a study using fluoroscopy during laryngoscopy of patients without cervical abnormalities. These authors proposed that direct laryngoscopy is potentially more hazardous in patients who have cervical instability that could be exacerbated by head movement. Tokunaga et al. (2006) also demonstrated a link between positioning of the head ideally for airway management, and vertebral subluxation in a population at high risk for spinal injury.

Hastings and Wood (1994) put best the issue of head movement during airway management of a potentially spinal injured patient by stating: “Because it is unknown how much head and neck movement is safe during direct laryngoscopy in patients with cervical spine injuries, minimizing the movement might make the anesthesiologist more secure about not causing harm.” (Hastings & Wood 1994 p 831). The minimization of head and neck movement during intubation is, and has been, a major goal for the management of the potential spinal injured patient. Identification of which patient is at risk for spinal injury could prove difficult due to the nature of the injury. Tokunaga et al.

(2006) pointed out that the absence of preoperative neurological symptoms does not assure perioperative safety. Also concerning is that when subluxation occurs during general anesthesia, neurological symptoms will not be apparent (Tokunaga, et al. 2006).

Head and Spine Immobilization

Suderman, Crosby and Lui (1991) stated, that the goal of manual in-line stabilization (MILS) is to stabilize the neck through a dynamic interplay such that an ideal amount of force is applied to offset the forces generated by the intubation (Suderman et al. 1991). In the following year, Walls (1992) described manual in-line stabilization as maintaining an existing relationship between the head and neck and between the neck and the body without the application of traction.

Crosby (2006) stated that the routine use of some form of immobilization during airway management of patients who are at risk of spinal injury is accepted by consensus as the standard of care. Crosby wrote that the goal of manual in-line immobilization is to apply sufficient forces to the head and neck to limit the movement that might result during medical interventions (Crosby, 2006). Crosby (2007) was more specific one year later stating, "The goal of manual in-line immobilization is to apply sufficient forces to the head and neck so as to limit the movement that might result during airway management" (Crosby, 2007 P 525).

Addressing the question of how effective and useful in-line spinal immobilization is in preventing secondary spinal injury is not a goal of this study. As indicated by Crosby (2006), spinal immobilization during airway management of patients is accepted

by consensus as the standard of care. Therefore, research should be conducted into airway management in the context of spinal immobilization and the interplay of both.

Spinal Immobilization and its Effect on Airway Management

Nolan and Wilson (1993) compared the ability to view the glottic structures of 157 patients both with and without spinal immobilization. They used the Cormack-Lehane system (Cormack & Lehane, 1984) to describe the exposure of the glottic structures. They reported that in 45% of subjects the graded view dropped at least one full grade with the application of spinal immobilization (Nolan, & Wilson, 1993). A follow-up study performed by Hastings and Wood (1994) corroborated reported findings consistent with Nolan and Wilson (1993). Heath (1994) reported similar findings in his work, also demonstrating a reduction in laryngoscopy view when a cervical collar was in place. The reason for this reduction was earlier postulated by Hastings and Marks (1991), later confirmed by Heath (1994), and found to be a reduction in mouth opening due to the cervical collar prohibiting jaw movement. Calder, Calder and Crockard (1995) demonstrated a link between cervical spinal disease and difficult intubation reporting a 20% incidence of difficult direct laryngoscopy in 253 patients undergoing surgery for cervical spinal disease. This was defined as a Cormack and Lehane grade three or four view. In this population, difficulty in intubation was attributed to cranial cervical rigidity and was aggravated by the patients' reduced ability to perform mouth opening. Goutcher and Lochhead (2005) corroborated these findings.

Calder et al. (2003) investigated this relationship between mouth opening, jaw movement and a reduction in the ability to view the glottic structures during direct

laryngoscopy. This group studied the association between craniocervical extension and mouth opening. They concluded that in order to achieve complete mouth opening, approximately 26-degrees of extension of the head from the neutral position is required (Calder et al. 2003). This can be postulated as one of the main mechanisms responsible for increased difficulty in intubating when spinal immobilization, with or without the use of a cervical collar, is used.

Manoach & Paladino (2007) authored an extensive review on the topic of manual in-line stabilization for airway management of suspected cervical spinal injured patients. As in previous studies, they found that manual in-line stabilization significantly worsened laryngoscopic view during intubation.

Crosby provided two extensive reviews of cervical spinal injury and airway management (Crosby, 2006; Crosby, 2007). His work stated that all airway maneuvers result in some degree of neck movement, both in general and specifically at the sites of injury. Crosby also stated that there is no published evidence that would indicate that one intubation technique is superior to any other *vis a vis* neurological outcome (Crosby, 2006). These statements are consistent with an editorial authored by Crosby earlier in 1992 where he stated,

> A hypothesis was generated that the airway of patients with unstable cervical spines could not be safely managed by oral intubation. Although there were no data at the time to support this thesis and none has been collected since, it was hypothesized that oral intubation was dangerous because it required excessive spinal movement, that this movement would

> lead to secondary injury and that it could be avoided by the careful performance of nasotracheal intubation or cricothyrotomy. This unsubstantiated hypothesis had achieved such a widespread degree of acceptance as to be labeled a "therapeutic legend of emergency medicine" by Rosen (Rosen & Wolf, 1989) (Crosby, 1992 p 106).

Crosby's statements point out the lack of research in both spinal immobilization as well as the lack of data supporting one method of intubation having advantages over other methods for either success of intubation or overall neurological outcome.

In summary, the prevailing view is that in the presence of spinal immobilization, intubation via direct laryngoscopy is more difficult with than without the use of spinal immobilization. This view provides the motivation to explore how best to minimize the difficulties imposed by spinal immobilization on the success of intubation. The study methods proposed here will reduce variability introduced in previous research in two ways. First, it will reduce variability introduced by the individual performing manual in-line stabilization. This was achieved by internalizing stabilization within the design of the model. Second, by providing a construct to compare one method of intubation against another, using a standardized model and methodology, a reduction in intra-study variability can be realized. Additionally, this study will provide a methodology for future evaluation of techniques of intubation and data generation that can be compared directly to data generated here.

Use of Simulation Models in Past Airway Research

Aprahamian, Thompson, Finger and Darin (1984) demonstrated that in a cadaver model, the act of airway management did produce significant movement of a surgically inflicted C5-C6 spinal injury. This study also showed that within this simulated injury model, the degree of spinal movement was related to the type of technique applied.

Lennarson et al (2000) developed a cadaver model designed to reflect the spinal motion of an injured patient during oral-tracheal intubation. The model was then used a year later in a study of the efficiency of spinal stabilization maneuvers during intubation (Lennarson, et al. 2001). Lennarson found that in-line stabilization effectively eliminated most cervical motion when applied during tracheal intubation.

The use of a cadaver model in medical research has limitations. Aprahamian et al. (1984) stated that the cadaver cannot represent a live patient with a cervical spinal injury adequately, but the cadaver model may provide some insight. As is the case with a cadaver model, no mannequin can adequately represent the anatomical subtleties or the characteristics of living tissue. In this research, the choice to develop and use a mannequin model has been made in order to reduce the amount of variability found within a patient population. The use of a mannequin allows the study to focus on variability attributable to the performance of the devices and its interplay with the provider rather than variables associated with live patients or cadavers.

Caplan, Posner, Ward and Cheney, (1990) suggested that simulation be used for clinicians to obtain concentrated exposure to relatively infrequent events, as in the case of difficult airway management. This ability to simulate difficulty in intubation was married

with the known relationship of spinal immobilization and glottic exposure degradation. Kihara, Yaguchi, Taguchi, Brimacombe and Watanabe (2005) used this type of simulation in their study. The degradation of the view of the glottic anatomy during intubation attempts in healthy volunteers was achieved through the application of in-line spinal stabilization. The authors used this method in studying two different airway techniques. This resulted in their study being conducted with in-line stabilization as a means of simulating difficult intubating conditions (Kihara et al, 2005).

The application of in-line stabilization has been used as a method of producing the conditions of difficult intubation in the past. This relationship may provide the basis for the application of the findings of the current study to the population of patients who are not suspected of having cervical spinal injuries but are suspected, for other reasons, of being difficult to intubate. This use of the data generated by the current study could expand the relevance of the findings to a larger population than that of spinal injured patients.

Measurement of Force in Past Airway Research

Chilcoat, Allen, Gerson and Grogono (1983) first described a laryngoscope handle capable of measuring forces applied during direct laryngoscopy. This device provided the user with a standard laryngoscope handle that could attach to any of the laryngoscopy blades available at the time. Housed within the handle of the laryngoscope were two modified strain gauges that could provide force feedback during intubation. This was the first device that allowed a quantitative analysis of force experienced by the patient while undergoing direct laryngoscopy. Although this manuscript described a

device, it failed to report any data generated. Three years later Rocco, Chatwani and Shupak (1986) presented a case report of a laryngoscope handle malfunction. They discussed the forces applied during a routine intubation as being roughly 10-30 Newtons but during difficult intubation, this force could increase to as much as 100 Newtons. Chatwani and Shupak credit this information to "Chilcoat RT, personal communication {sic}". Although not stated, it is assumed that the data attributed to Chilcoat by Rocco et al. was obtained using the device described three years earlier by Chilcoat et al. (1983). This measure of force was reported in the international standard units of Newtons. The Newton is a derived unit defined by the International Committee for Weights and Measures and is expressed as kilograms times meters per seconds squared ($kg \cdot m/s^2$). Using a balance scale, one Newton will balance 100 grams. Extending this for the purposes of understanding, 10 Newtons = 1 kg. Therefore, 10 Newtons is approximately equal to 2.2 pounds of force.

Bishop, Harrington and Tencer (1992) reported a peak force of 48 Newtons with direct laryngoscopy. These authors used a laryngoscope and a Macintosh 3 blade that was modified with strain gauges to quantify the forces used to intubate both patients and a standard Laerdal Airway Trainer Mannequin. This study correlated the force generated in both patients and a mannequin using a single device for force measurement. They compared the effectiveness of experienced and novice providers for force and time required to intubate. They reported finding that the force recorded for intubation of the mannequin was consistently greater then that for actual patients. This was attributed to the characteristics of the plastic tongue found in the mannequin (Bishop et al. 1992).

These findings demonstrate an overestimate of the force actually needed to accomplish the same intubation in a living patient. This over estimation of force could be viewed as a margin for safety, if we accept as fact that the forces actually required in a real patient were less. Interestingly, this over estimation was consistently displayed within the mannequin data. Knowledge of this consistency in mannequin-derived data may allow for predictable comparison of mannequin data to real patient circumstances.

Bucx, Scheck, Van Geel, Den Ouden and Niesing (1992) described a laryngoscope handle that was capable of quantifying the forces used during intubation. As in past research into the topic, these researchers used a laryngoscope handle that incorporated a strain gauge. This group reported finding a mean of 20 Newtons and a maximum force of 35 Newtons during the intubation of 49 adult patients (Bucx et al. 1992). Bucx, Van Geel et al (1994) reported a finding of 25 Newtons in 54 children ages 2-15 during laryngoscopy. The findings reported here were consistent with Chilcoat's earlier findings of routine intubation forces measured at roughly 10-30 Newtons as reported by Rocco et al. (1986).

Bucx, Van Geel, Wagner, Robers and Stijnen (1995) then used the device described in 1992 by Bucx, et al. to evaluate the influence of provider experience and type on forces exerted against the teeth of a mannequin model. This group reported that the level of experience has a significant influence on the duration of laryngoscopy but seemed to have little influence on the forces applied to the tongue and incisors. These findings seemed to indicate that the forces required to achieve intubation are independent and unrelated to the type of provider performing the technique in a mannequin model.

However, the lack of coupling between force and provider type may or may not hold true when comparing provider type and the interaction of differing techniques for intubation.

McCoy, Austin, Mirakhur and Wong (1995) published an article describing a new device for measuring and recording the forces applied during laryngoscopy. As in past attempts, the device used was a standard laryngoscope handle modified by the addition of strain gauges to detect directional loading. This device allowed direct laryngoscopy to be performed in its normal manner while using any compatible laryngoscopy blade attached to the laryngoscope handle. This device was tested in 40 patients resulting in a maximum force reported of up to 60 Newtons (McCoy et al. 1995). The following year McCoy, Mirakhur, Rafferty, Bunting and Austin (1996) used this device to compare the forces encountered during intubation using two differing blade types. The standard Macintosh blade was compared against the performance of the newer McCoy blade. The study demonstrated a 53% reduction in force with the use of the McCoy blade over the Macintosh blade. The reduction of force found with the McCoy blade was attributed to the blade's ability to elevate the epiglottis via a lever while decreasing the overall laryngoscopic movement (McCoy et al. 1996). This study demonstrated that the amount of force could vary significantly with the type of technique used to achieve the intubation process.

Hastings, Hon, Nghiem and Wahrenbrock (1996) reported that in 58 patients an average peak force was measured at 38 Newtons. For 50 of the 58 patients, this peak was found to decrease by 30% over 15 seconds resulting in a plateau. This group postulated that this finding was due to the passive stretching of pharyngeal tissue during

laryngoscopy. The authors further postulate, "…laryngoscopists might be advised to apply force slowly to reduce the peak force necessary for vocal cord exposure" (Hastings et al. 1996 p 461). This hypothesis has yet to be tested.

Keller, Brimacombe and Keller (1999) studied the pressure exerted by an Intubating Laryngeal Mask Airway (ILMA) on the cervical vertebra by placing subcutaneous microchip pressure sensors in the airway of fresh cadavers. This was the first time that a mechanism to measure the presence of force was placed in the model, in this case a human cadaver, rather than in the device being tested itself. This group found that a greater degree of force was being exerted with the use of an ILMA than that being found with standard laryngoscopy.

Evans, Vaughan, Hall, Mecklenburgh and Wilkes (2003) attempted to compare the force exerted during laryngoscopy using disposable and non-disposable laryngoscope blades. This group took the novel approach of measuring forces by placing a Laerdal Airway Management Trainer mannequin on a mass balance scale. This allowed for the forces made in an upward motion during laryngoscopy to be measured by the mass required to balance and oppose that force. This study then performed 600 intubations made by 60 different providers and reported a significant difference in force based on whether the laryngoscope blade was plastic or metal. Their findings showed that metal blades provided less force then the plastic disposable types. No difference in force was noted concerning training levels of providers (Evans et al. 2003). Their finding regarding the influence of training level on force was consistent with the finding of Bucx, Van Geel et al. (1995). The approach used by Evans et al. to measure force could, in theory,

provide a means of comparing different types of intubation devices rather than just the type of blades tested in this study. The mannequin model used for this study incorporates the ability to quantify the degree of force being applied in a downward vector simultaneously with the forces being used to elevate tissues during laryngoscopy. This is not the case in the model used by Evans et al.

Hashemi, Soltoni, and Saeid (2004) attempted to measure directly the forces applied to the base of the tongue by the tip of a number three Macintosh laryngoscope blade and their relationship to post-operative sore throats. Interestingly, Hashemi et al. employed a method similar to the method used in the creation of the mannequin model for the current study. These researchers secured a small non-compliant plastic balloon on the tip of a # 3 Macintosh laryngoscope blade. This balloon was then connected through non-distensible tubing to a transducer for pressure measurements in a similar configuration as the mannequin designed for this research. In their study, the researchers chose to use air as the fluid medium against which pressure was exerted, transmitted and transduced (Hashemi, et al. 2004). The authors offer no discussion regarding the nature of the compressibility of the medium fluid, in this case, air. This compressibility can potentially introduce wide variability into their pressure data. In the model for this study, saline solution was used in a similar pressure transduction configuration in order to decrease this variability.

The nature of pressure transduction systems for direct medical pressure monitoring has been discussed by Gardner (1981) as well as Loeb and McCoy (2000). Loeb and McCoy (2000) authored an entire chapter on the subject of pressure

transduction, providing the underpinning for the current study. The accuracy and reliability of disposable pressure transducers was determined by Gardner (1996) to be ± 2%. This was found to be below the accepted ± 3% standard set by the American National Standards Institute for disposable transducers (Gardner, 1996).

Santoni et al (2009) reported the construction of a pressure-sensing laryngoscope blade that was constructed by placing six sensors along the surface of a standard # 3 Macintosh blade. This device was then used to quantify the amount of pressure used during direct laryngoscopy with and without in-line stabilization. In this study, the authors first used a Laerdal Airway Management Trainer mannequin to test this measurement tool. They determined that in the mannequin a 465 mmHg mean difference between direct laryngoscopy with in-line stabilization compared to laryngoscopy without in-line stabilization was present. Their findings clearly showed a significant increase in the amount of force employed when in-line stabilization was used. This group then used the same methodology in ten healthy patients. They reported that the application of in-line stabilization resulted in a near doubling of the force seen when compared to laryngoscopy without in-line stabilization (Santoni et al. 2009). The mean difference was reduced to 354 mmHg between direct laryngoscopy with in-line stabilization compared to laryngoscopy without stabilization in healthy patients. This overall reduction in the measured force between a mannequin and healthy patients was consistent with the findings made earlier by Bishop et al. (1992). In an accompanying editorial, Manoach and Paladino (2009) pose the question, should we modify the practice of manual in-line stabilization in light of the finding of Santoni et al (2009). This question will continue to

be debated, although in their summation, Manoach & Paladino state that, "Because intubation guided by direct laryngoscopy is familiar, effective, and fast it will persist" (Manoach & Paladino. 2009 p7).

The literature does not support a standard measurement of force or pressure during the intubation process. However, it would appear that a range of approximately twenty-five to forty-five Newtons is common to at least four of the reported maximum pressure measures for direct laryngoscopy using either a Miller or Macintosh blade. Of note, at least two studies reported much higher values of sixty and in one case one-hundred Newtons. This wide a range in the findings raises the question of the source of the variability. The nature of this variability can be postulated as having such sources as, patient factors, the type and nature of the provider, and varying techniques for performing the measurement,

Past Comparison of Techniques and Devices for Airway Management

Shwiry, Joseph, Sullivan and Gotta (1983) demonstrated the interest by CRNAs and other anesthesia providers in exploring the placement of an endotracheal tube by other methods than direct laryngoscopy in patients who are spinal immobilized. In this case-series, the use of both a superior laryngeal nerve block and a transtracheal block was used to facilitate blind nasal intubation in an attempt to minimize spinal movement associated with standard intubation techniques (Shwiry, Joseph, Sullivan & Gotta 1983).

Meschino, Devitt, Koch, Szalai and Schwartz (1991) reported in a case control series of more than 300 patients having cervical spinal injury that tracheal intubation while awake was safe. In this study, all patients were awake at the time of intubation.

Twenty-two percent of the intubations were performed via direct laryngoscopy, 32% were blind nasal, and 46% of the treatment group was intubated via the use of fiberoptic bronchoscopy. Manninen, Lukitto, Venkatraghavan, and Beheiry (2007) studied the relationship between intubation technique and preoperative clinical presentation. This was conducted in a population presenting for spinal surgery over a 30-month period. Not surprisingly, they reported awake fiberoptic bronchoscopy (FOB), this technique is the same as FOI, was the most likely choice followed by asleep FOB, asleep laryngoscopy and other asleep techniques. They postulated that this was due to an assumption by those providers of airway care that FOB allowed for the patients with cervical spine injury to remain in a neutral head position during intubation (Manninen et al, 2007). Although these studies appear to demonstrate safety via awake intubation, Peterson et al. (2005) reported that failed awake intubation had been identified by the ASA Closed Claims Project as a major cause of morbidity and mortality.

Majernick, Bieniek, Houston and Hughes (1986) reported finding no statistical difference between laryngoscopy using a Miller blade when compared to a Macintosh blade in regards to cervical spine movement. LaGrand, Hindman, Dexter, Weeks and Todd (2007) compared craniocervical motion during laryngoscopy using the Macintosh and Miller blades. The findings of their study demonstrated that the Macintosh blade was associated with a greater degree of movement of the cervical spine during laryngoscopy then was the Miller blade (LaGrand et al. 2007). These authors postulated that laryngoscopy using the Miller blade resulted in a glottic position that was less anterior and caudal than with a Macintosh blade. LaGrand et al. (2007) stated that the difference

between the two blades was statistically significant, although the difference was so small it was thought not to have clinical relevance.

Kihara et al (2000) studied the movement of the cervical spine during intubation using the ILMA Fastrach in patients with cervical pathology. These authors reported that cervical spinal movement was present even with in-line stabilization when the ILMA was used. Brimacombe et al. (2000) examined the performance of different airway management techniques using fluoroscopy in a cadaver model with posterior destabilized cervical vertebra. The techniques tested were direct laryngoscopy, nasal fiberoptic intubation, the Combitube, the Laryngeal Mask Airway and the Intubating Laryngeal Mask Airway. They reported the presence of segmental movement for all techniques tested but it was considerably less for fiberoptic intubation (Brimacombe et al. 2000). In the uninjured non-immobilized patient, Sahin, Salman, Erden and Aypar (2004) documented a greater amount of spinal motion using video-fluoroscopy with direct laryngoscopy than with the ILMA Fastrach. Sahin et al. (2004) documented the least amount of motion with the use of the flexible fiberoptic laryngoscope.

Agro, Barzoi and Montecchia (2003) studied the performance of the GlideScope® compared to a Macintosh laryngoscope in fifteen patients undergoing general anesthesia with cervical collars in place. These authors found that in fourteen of the fifteen patients the GlideScope® provided a better view of the glottic structures by one full Cormack and Lehane grade. In 36 patients presenting for general anesthesia, Turkstra, Craen, Pelz and Gelb (2005) compared spinal motion while using the Macintosh blade, Trachlight® and GlideScope® with in-line stabilization. They found that using the Trachlight® reduced

spinal movement during endotracheal intubation as compared with the use of the Macintosh laryngoscope blade. Although the GlideScope® performed as well, if not better, than the Trachlight® regarding spinal movement, it was associated with a 62% longer time requirement to achieve intubation. Robitille et al. (2008) compared the amount of cervical spinal motion while performing intubation using direct laryngoscopy versus the GlideScope®. They reported that the GlideScope® provided an enhanced glottic view when compared to direct laryngoscopy. This group found little difference concerning spinal movement between the two techniques (Robitille et al. 2008). This seemed to indicate that abolishing the need for a direct line of sight to the glottic opening has little effect on spinal motion in healthy uninjured subjects undergoing intubation. This result may reflect more on how the GlideScope® was used and by whom. In this study, two residents conducted all intubations having performed the "technique 30 times" prior to the study. This may suggest that novices who use indirect optic devices that have similarities to laryngoscopes do so in a similar manner. This finding may be due to past experience with standard laryngoscopes and may not be inherent to the device.

Maharaj, Higgins, Harte and Laffey (2006) evaluated the Airtraq and the Macintosh laryngoscope blade in a mannequin. One year later, Maharaj, McDonnell, Harte, and Laffey (2007) studied novice providers using a mannequin to compare direct and indirect laryngoscopy as well as the ILMA by novice users. These authors point out that devices such as the McCoy laryngoscope, the GlideScope®, the Airtraq device, the ILMA, and the conventional Macintosh laryngoscope have been studied individually, but

these devices have not been systematically compared in a single study (Maharaj et al. 2007). This research will address this need.

The interest in comparing one device to another continues to be studied and research has been conducted by Maharaj, Buckley, Harte, and Laffey (2007). Their study tested the Airtraq device against the direct laryngoscope using a standard Macintosh blade in 40 patients being intubated with manual in-line spinal stabilization. The findings support superior intubating conditions with the Airtraq. The study also stated that further comparative studies are needed to determine the relative efficacies of airway devices. Maharaj stated, "The Airtraq provides a view of the glottis without a need to align the oral, pharyngeal, and tracheal axes, and therefore requires less force to be applied during laryngoscopy." (Maharaj et al. 2007 p 58). This desire to gain a view of the glottic anatomy by other then direct means is the underpinning for the use of indirect laryngoscopy techniques.

Summary

There are several noteworthy limitations in the research presented above. First, no single method has been consistently used to evaluate the performance of the varied airway devices and techniques. Perhaps this is due to past efforts focusing on modifications made to the laryngoscope handle as a means of force measurement. This, by definition excludes the comparison of all methods not utilizing a laryngoscope handle. Secondly, past studies have employed mannequin, cadaver and both healthy and injured subjects. This makes interpretation and cross comparisons difficult due to the varying experimental conditions. Thirdly, previous studies have used varying radiologic methods

to compare spinal movement during airway management techniques. Radiographic interpretation and a lack of standard application of measurement techniques have been cited as limitations in several studies. The meaning and relevance of this methodology also has continued to be plagued by the lack of a defined standard of acceptable spinal movement for a patient who may have a spinal injury.

In light of these limitations in the literature, there is a need for more empirical research that will allow us to reach definitive conclusions with regard to the issues surrounding airway management. In particular, there is a need for an experimental method and design, such as the ones proposed here, that employs a single, multi-device, multi-provider, approach. Such an approach will allow for meaningful comparisons, while controlling for many of the variables mentioned in the literature. An additional benefit of an experimental design such as the one found in this study is the increased ability to generalize the research findings generated from such an approach. This need was addressed within this research. The heart of this research is the creation and eventual validation of a means of quantifying the amount of force experienced by a patient during airway management. This was accomplished by the use of a patient simulation mannequin that provides force feedback. This approach to force measurement is novel. By creating a mannequin that serves as the measuring tool rather than instrumenting the device used to manage the airway, as in past research attempts, the ability to make cross comparisons of devices as well as other variables can be realized. This research used a more sophisticated experimental design and employed a multivariate statistical technique that is apparently not found elsewhere in the literature. This research has the potential of

being able to bridge the gaps found in the literature by providing a means of assessing multiple methods of airway management techniques and the interplay of provider type on the forces employed.

CHAPTER THREE

Research methods are presented here in Chapter Three. A discussion of protocols for measuring pressure is also provided, as are preliminary analyses leading to a final research and statistical design.

Discussed previously, the purpose of this study is the development of an experimental model that allows for multi-device, multi-technique, and multi-provider assessment of pressure and thereby, the forces associated with interventions related to airway management. The foundation of this research is to develop, and assess the validity and reliability, of a method of quantifying the force experienced by a patient during airway management, in order to inform better the clinical practice. By creating a mannequin that serves as the measuring tool rather than instrumenting the devices used to manage the airway, the ability to quantify and allow for reproducible cross comparisons of devices as well as other variables can be realized.

A review of the study objectives, research questions, and hypotheses is presented here

Objectives

1. To develop an intubation model with the means of quantifying the forces experienced by a patient undergoing the placement of an endotracheal tube..

2. To develop an intubation model that simulates the difficulty commonly encountered in spinal immobilized patients.
3. To then test the experimental model in varying geographical locations with differing clinical providers using a variety of airway management techniques and in that process, assess the validity and reliability of the model.

Operational Questions

The operational research questions prior to data collection of this study were the following:

Is there a statistically significant difference in maximum pressure and time required for intubation between:

1. Six different airway techniques.
2. Three different clinical practitioner types.
3. Five different geographical locations.
4. The interactions of the six techniques by the three practitioners.
5. The interactions of the six techniques by the five locations.
6. The interactions of the three practitioners by the five locations.
7. The interactions of the six techniques by the three practitioners by the five locations

Hypotheses

Hypothesis 1. There will be a statistically significant difference in mean maximum pressure for each of the six different techniques.

Hypothesis 2. There will be a statistically significant difference in mean maximum pressure for each of the three different practitioner types.

Hypothesis 3. There will be no statistically significant difference in mean maximum pressure for each of the five locations of data collection.

Hypothesis 4. There will be a statistically significant difference in mean maximum pressure for each of the six different techniques by each of the three different practitioner types.

Hypothesis 5. There will be no statistically significant difference in mean maximum pressure for each of the six different techniques by each of the five locations of data collection.

Hypothesis 6. There will be no statistically significant difference in mean maximum pressure for each of the three different practitioner types by the five locations of data collection.

Hypothesis 7. There will be a statistically significant difference in mean maximum pressure for each of the six different techniques by the three different practitioner types by the five locations of data collection.

Hypothesis 8. There will be a statistically significant difference in the time required for intubation for each of the six different techniques.

Hypothesis 9. There will be a statistically significant difference in the time required for intubation for each of the three different practitioner types.

Hypothesis 10. There will be no statistically significant difference in the time required for intubation for each of the five locations of data collection.

Hypothesis 11. There will be a statistically significant difference in the time required for intubation for each of the six different techniques by the each of the three different practitioner types.

Hypothesis 12. There will be no statistically significant difference in the time required for intubation for each of the six different techniques by each of the five locations of data collection.

Hypothesis 13. There will be no statistically significant difference in the time required for intubation for each of the three different practitioner types by the five locations of data collection.

Hypothesis 14. There will be a statistically significant difference in the time required for intubation for each of the six different techniques by the three different practitioner types by the five locations of data collection.

A statistically significant difference is defined as a difference with a 95% confidence.

Methodology and Research Design

Mannequin Modifications

A standard Laerdal Airway Trainer Mannequin that can be seen in Figure 4 was modified in the following way. As a first step, all attachments were removed from the mannequin. These attachments included the esophagus, stomach, lung support mechanism and the lungs. The mannequin was then released from its mounting board using the manufacturer's installed releasing mechanism. Once this was completed, full access to all areas was permitted. The neck of the mannequin was then detached from

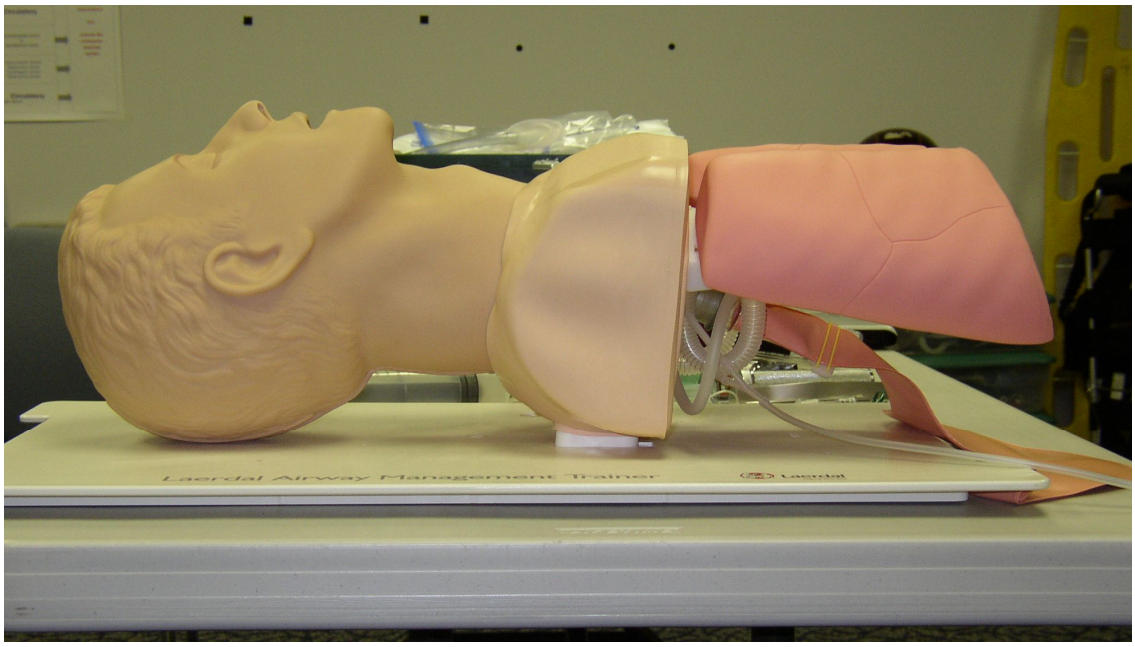


Figure 4. Laerdal Airway Management Trainer

the rotational swivel mount of the thorax and can be seen in Figure 5. This was accomplished by releasing the three mounting screws that secure the neck to the mannequin's thoracic component.

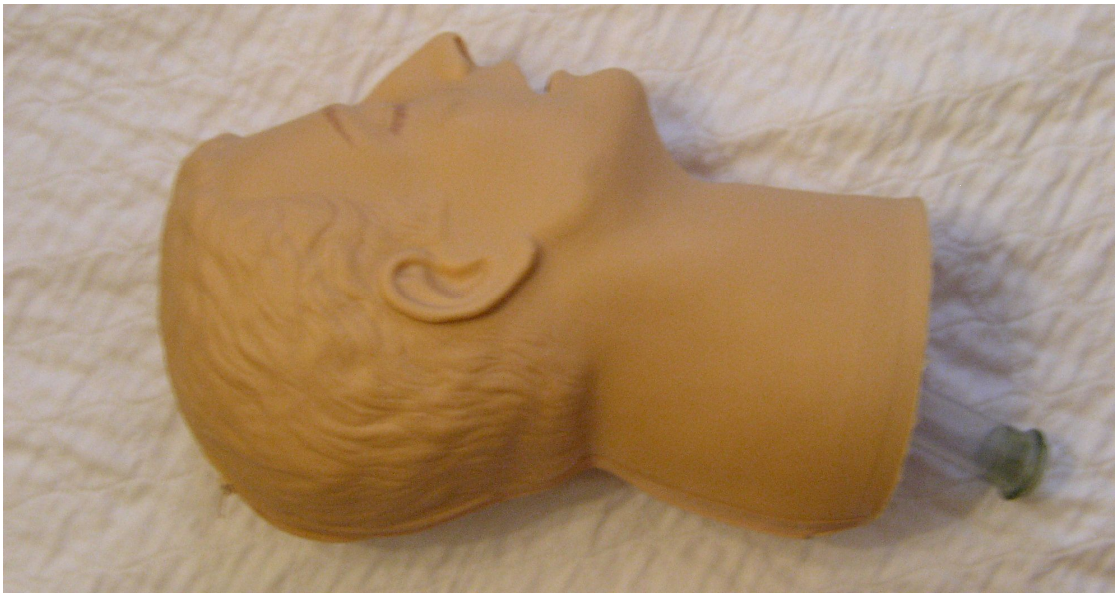
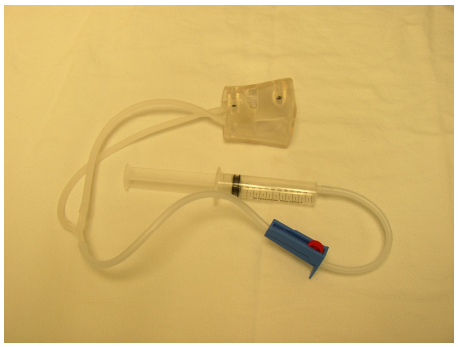
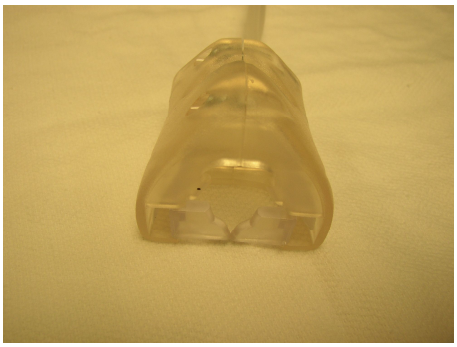


Figure 5. Head and Neck of Mannequin

With the head assembly removed from the thorax, access to the zipper located on the posterior surface of the head could now be obtained. This zipper secures the external latex skin of the head and neck over the internal skeletal structures of the mannequin. Once the skin was inverted, care was taken to preserve the seal between the airway structures and the skin. This seal is made of latex glue and serves as the union between the external skin and the internal components of the mannequin's oral cavity. With the skin peeled back and remaining in place, the neck of the mannequin was dearticulated from the head at its two pivot points. This exposed the laryngeal structures of the mannequin. The two air chambers and plastic assembly that allow for the movement of the vocal cords when one squeezes a syringe were then removed (See Figures 6 and 7).

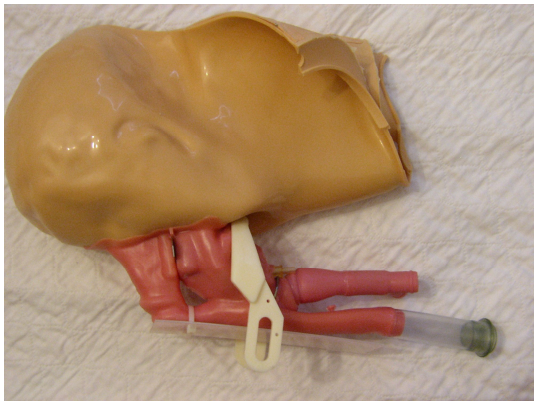




Figures 6 and 7. Vocal Cord Assembly

The lower jaw of the mannequin was also disarticulated from the cranium. The two screws securing the teeth were removed from the underside of the mannequin's lower jaw and the jaw and teeth were dearticulated and removed. Finally, the four screws securing the two halves of the cranial cavity were removed. This allowed for the complete separation of the skin and bonded airway structures from the internal skeletal

structures of the mannequin (Figures 8 and 9). The two sandbags found in the cranium that provide weight simulation to the cranium were also removed.



Figures 8 and 9. Mannequin Skin and Head Assembly

The first modification made to the mannequin began with the construction of a steel bracing system capable of stabilizing and maintaining the neck, head and torso of the mannequin as a single rigid unit (See Figure 10). This bracing, once mounted in the mannequin, prevents the movement of the head in both extension and flexion.

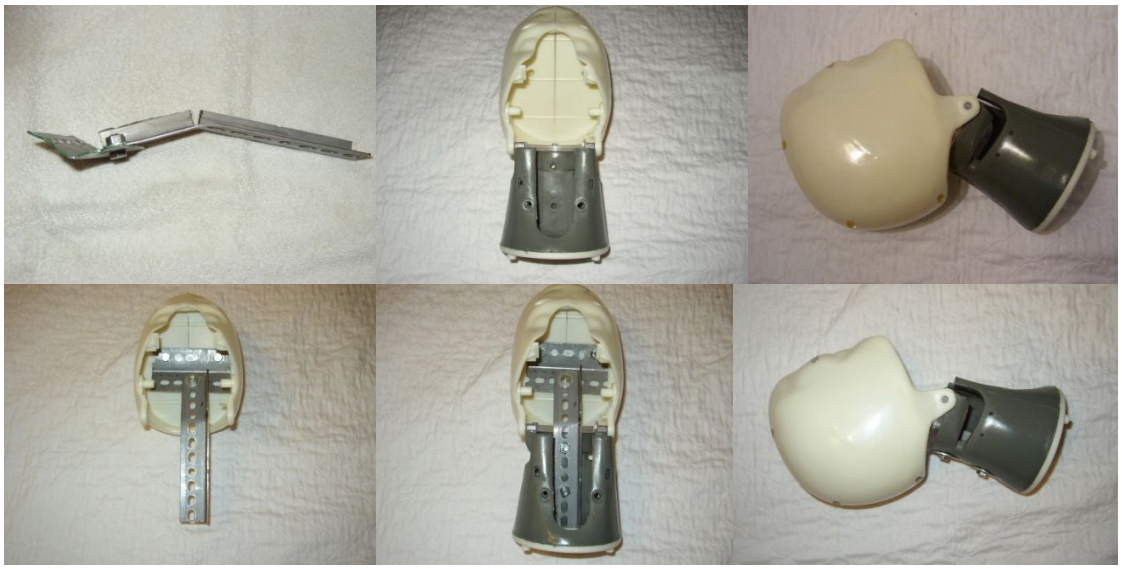


Figure 10. Internal Bracing of Mannequin Cervical Spine

This was undertaken in an effort to simulate and standardize the application of spinal immobilization. Two pieces of one and one-half inch perforated steel angle iron were cut to fit the width of the inferior surface of the cranium and the length of the neck. They were then fastened together using one one-quarter inch bolt. Two one-quarter inch holes were drilled through the internal inferior surface of the mannequin's cranium. The bracing assembly was then mounted to the internal and inferior surface of the cranium using two one-quarter inch bolts as shown in Figure 10. Rubber washers were placed between the bolts and the plastic cranium in order to minimize the risk of compressing or fracturing the plastic. Only one of the two sandbags was returned to the cranial cavity. This was reduced from the two normally found in the cavity in order to compensate for the increase in weight due to the addition of the steel bracing. With the bracing now secured to the head, the neck and head were rearticulated. The neck portion of the bracing was then manipulated to allow the head and neck to assume a neutral position once reassembled as can be seen in Figure 10. Two holes were then drilled through the posterior portion of the neck matching the perforations of the bracing. The bracing was then secured to the neck of the mannequin by two ¼-inch bolts.

The next modification began with the latex skin and oral cavity assembly. By bluntly dissecting the tongue from the oral cavity at the sublingual surface, access was achieved to the internal chamber of the mannequin's tongue. Next, the oval shaped open cell padding found in the tongue was removed. The cavity within the tongue was then filled with an evacuated 25-milliliter polyvinyl intravenous fluid bag. The outer surface of the oral cavity was pierced and the intravenous port was then externalized into what

would be the interstitial space, located in the space between the airway and the skin of the mannequin. The sublingual space was then repositioned as before and sealed using a latex sealant. The lower jaw and teeth were reassembled using the two screws as mentioned previously and rearticulated with the cranium. The skin and airway assembly was then placed back in the original position and re-affixed to the skeletal structures as it had been originally found as can be seen in Figure 11. The externalized intravenous port was then connected to non-distensible tubing and sealed with latex sealant.

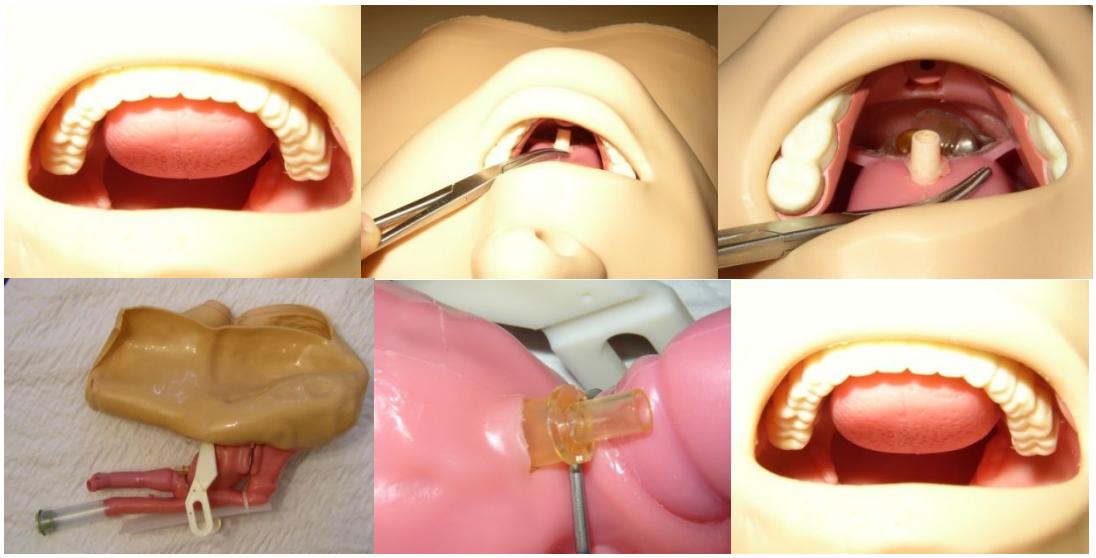


Figure 11. Lingual and Sublingual Space of Mannequin

The next modification was made by placing an evacuated 50-milliliter polyvinyl intravenous fluid bag over the laryngeal structures of the airway at the level of the vallecula. This location correlates with the interstitial space located between the outer surface of the airway and the inner surface of the skin of the mannequin. The intravenous port was then connected to non-distensible tubing and sealed with latex sealant. This bag was secured in place using Coban self-adherent elastic wrapping (3M Corporation, St.

Paul, MN) that was placed circumferentially around the neck of the mannequin internal to the skin (See Figures 12 and 13). This circumferential wrapping allows for compression of the compartment when force is applied to the internal structures of the airway.

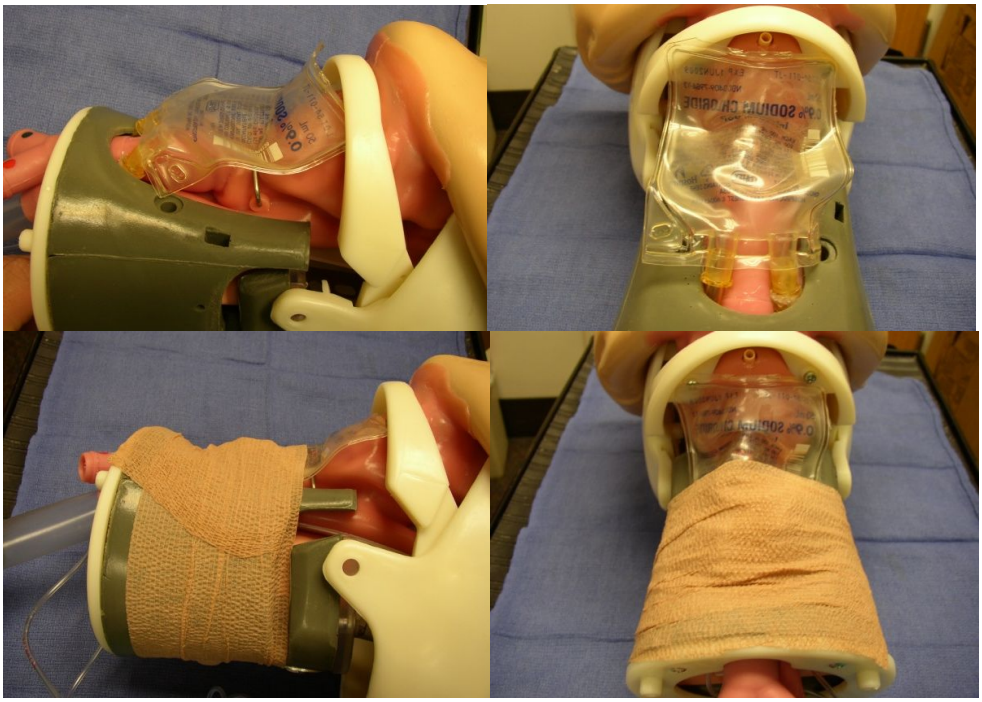


Figure 12. Vallecula and Interstitial Space of Mannequin

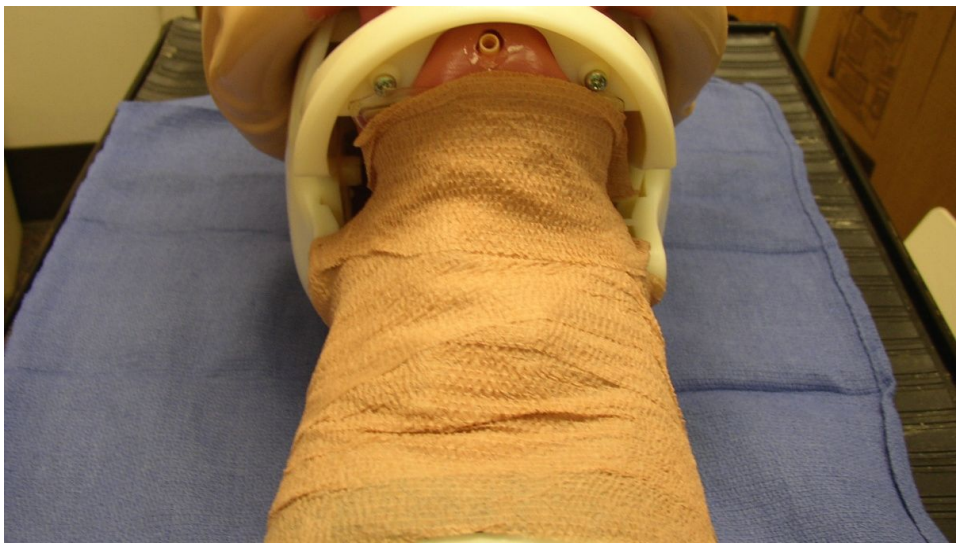


Figure 13. Interstitial Space of Mannequin

With the preceding alterations complete, the mannequin was then reassembled. The skin was replaced and the zipper secured. The head and neck were assembled once again onto the mounting swivel located in the thorax and secured with the three screws. The two non-distensible tubings were externalized through the same common port that allows for the trachea and esophagus to exit and affix to the lungs and stomach of the mannequin.

The mannequin was then reattached to the mounting board using the manufacturer's installed mechanism.

A final modification was made by securing an evacuated 250-milliliter polyvinyl intravenous fluid bag between the mounting board and the mannequin's head. This bag was mechanically secured to the mounting board using Velcro. The Velcro was attached to both the bag and the mounting board with adhesive. This permits the head of the mannequin to rest on this fluid compartment. This configuration will capture forces applied to the mannequin in a downward posterior vector, resulting in compression of the saline bag between the mannequin's head and the mounting board. The intravenous port of the bag was then connected to non-distensible tubing and sealed with latex sealant as seen in Figure 14.

Each piece of the non-distensible tubing was then connected to a separate three-way stopcock mounted onto a manifold. The manifold held three medical quality piezoelectric pressure transducers commonly used to measure physiologic pressure (see Figure 15). This configuration allowed for independent pressure monitoring from each of the three fluid compartments. Each compartment is capable of being recalibrated to zero.

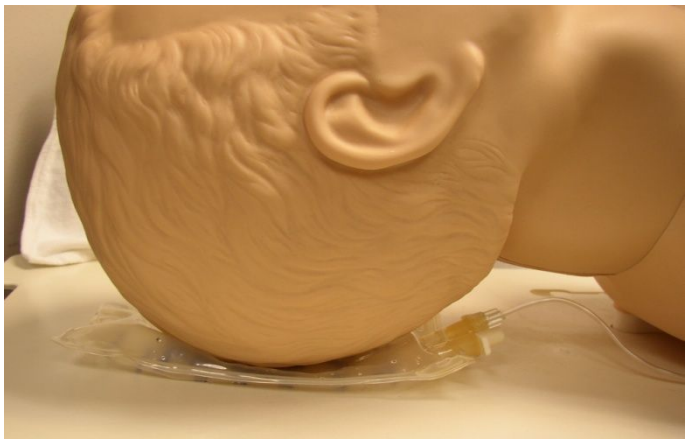


Figure 14. Head and Mounting Board

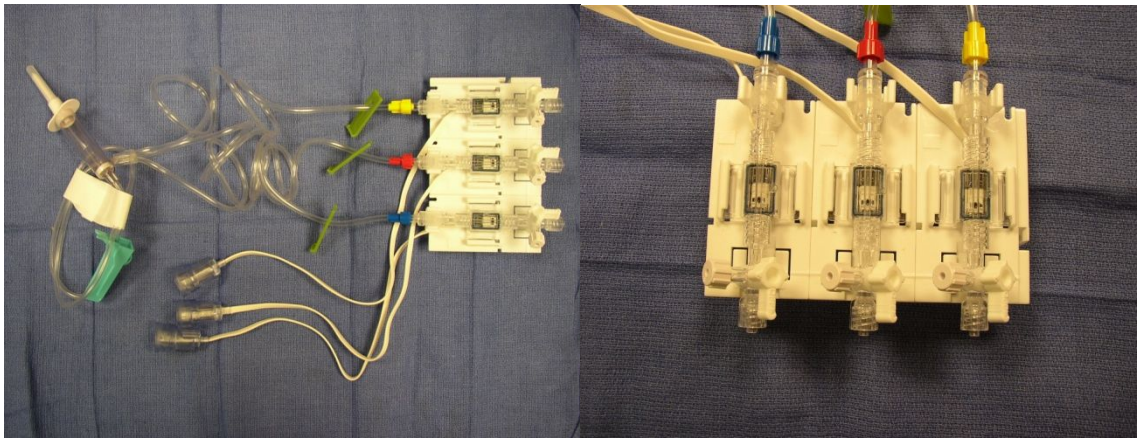


Figure 15. Pressure Manifold

This zero calibration was conducted as part of the research protocol before each subject was tested.

Prior to data collection, each of the three compartments was filled via a 60 ml syringe using medical grade saline solution held at room temperature for greater than one hour. The mannequin was placed in a head down position and agitated. By agitating the mannequin the evacuation of all air throughout each of the three chambers and tubing was achieved via the three-way stopcock. This air was then replaced with a medical grade

saline solution (See Figure 16). The volume placed in each compartment was only sufficient to provide five mmHg of pressurization as a baseline, allowing for a minimal amount of distention of each compartment prior to the application of external force. This distention served to insure that forces applied are truly representative of increasing pressure within that compartment.

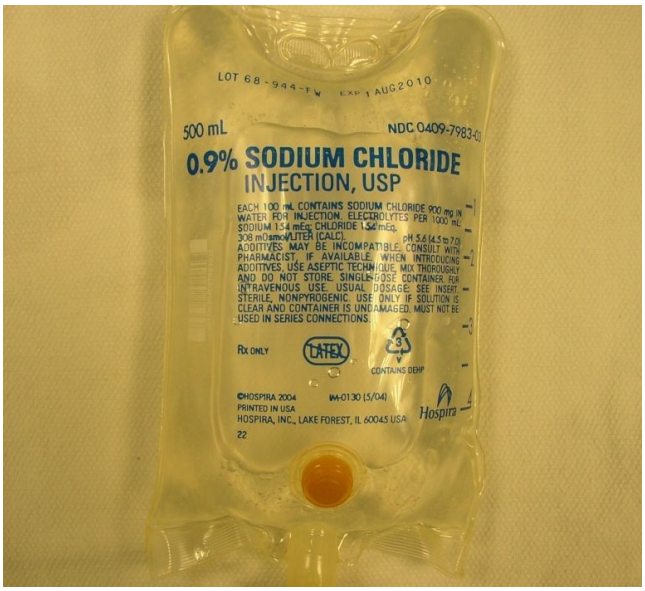


Figure 16. Medical Grade Saline Solutions

Once a baseline pressure of five mmHg was achieved, each compartment was electronically recalibrated to zero. This recalibration was repeated just prior to all measurements to assure accuracy and reliability of each measurement. Maximum force exerted against each compartment during instrumentation was recorded electronically. The highest pressure recorded from any one of the three locations was documented and used for subsequent data analysis.

Study Phase One

After obtaining approval from the University of North Carolina at Chapel Hill and the Virginia Commonwealth University Institutional Review Boards, thirty volunteer subjects were recruited at the University of North Carolina, Department of Anesthesiology. All subjects were from one of the following three categories: anesthesiology resident physicians who have completed greater than two years of training, staff certified registered nurse anesthetists, and attending anesthesiologists. Informed consent was obtained from all subjects prior to their participation.

Two mannequins were held in place on a standard worktable side-by-side affixed to the table using two six-inch C-clamps. The first mannequin was an unaltered Laerdal Airway Management Trainer® and the second was the altered model described above. Subjects were then assigned to one of two groups in order to determine which of the two mannequins they would intubate first. This assignment was made by the use of a random number generator set between zero and two. It was intended to provide a balanced design and minimize experimental error. Fifteen of the thirty non-consecutive subjects performed their first intubation attempt on the unaltered mannequin; the subject then intubated the model created for this research. Alternatively, the other fifteen non-consecutive subjects performed their first intubation attempt on the research model, followed by intubating the unaltered mannequin. Both models were presented as displaying no outward difference. Sham tubing and monitor cables from the unaltered mannequin were placed to insure similar appearance of each model. This was undertaken in order to minimize subject bias towards the experimental model. Both models were

presented with the rear portion of a cervical collar in place in order to simulate the intubation of the spinal-immobilized patient. Each subject was told that the nature of the experiment was to assess the mannequins for future teaching of airway management regarding the spinal-immobilized patient. Subjects performed intubation using a standard laryngoscope with a Macintosh 3 blade and a 7.0-millimeter internal diameter endotracheal tube. Each subject was asked to perform the intubation and then to self-rate the amount of force used during the intubation. Unknown to each subject, an independent observer who was administering the test documented his perception of the force used by each subject for each intubation. The rating of the amount of force was conducted on a three-point scale consisting of "minimal, moderate and significant."

Pressure Sensing Locations within the Research Mannequin.

For all subjects tested in both phase one (N=30) and the main portion of this research (N=102) the maximum pressure recorded by any one of the three sensing locations during the intubation process was found to be in the location of the tongue. The next highest pressure reading obtained was at the level of the vallecula, and finally, the least of the three was between the mounting board and the mannequin's head (See Figure 17.) This was true for all techniques, locations and provider types as well as all combinations. As defined previously, only the maximum pressure reading of the three different sensing locations within the mannequin were used for data analysis, thus the pressure reading from the tongue was the dependent variable (DV) used for this study. This means that the pressure data used in both phase one and the main portion of this research was obtained from the location of the mannequin's tongue as seen in Figure 17.

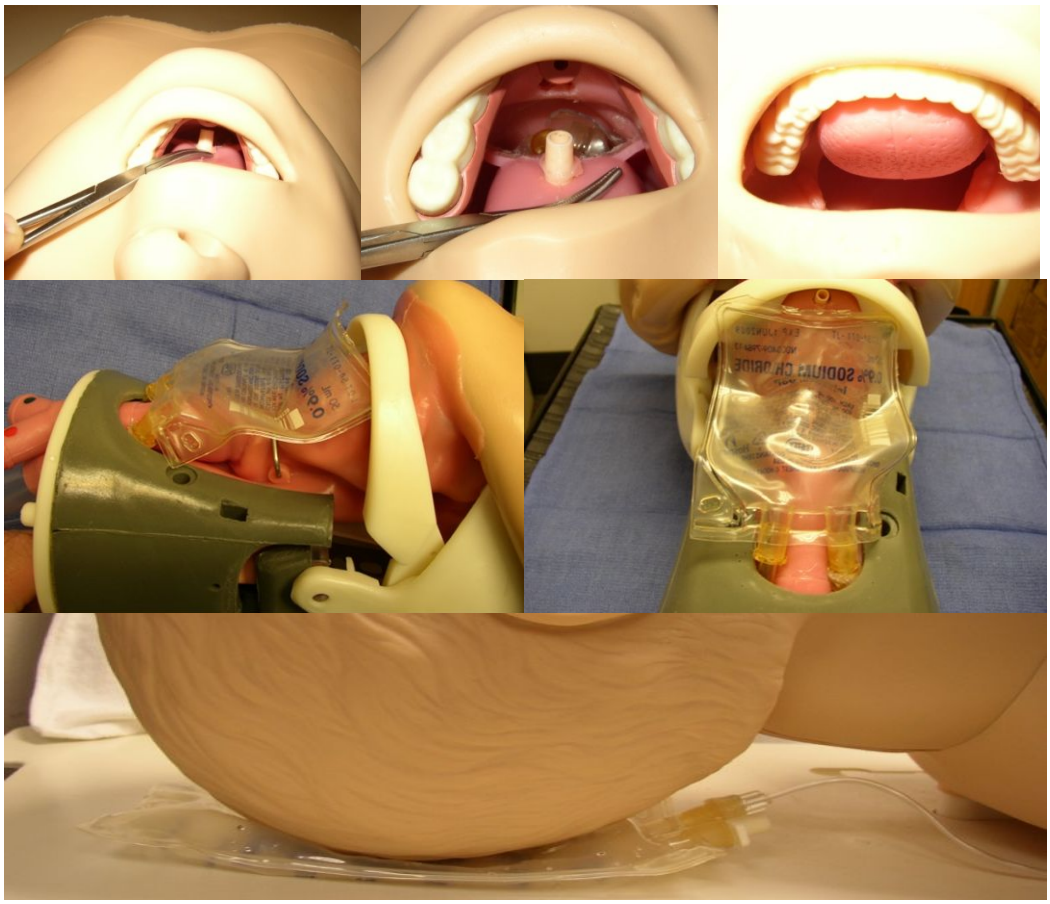


Figure 17. Pressure Sencing Locations for the Research Mannequin

Results of Phase One.

A schematic representation of this portion of the research, as well as a photo of the actual setup of the side-by-side testing can be seen in Figures 18 and 19.

	Unaltered Mannequin		Altered Mannequin	
	X_1		X_2	
15 Subjects →	$(O_1\text{-}O_2)$	>	$(O_1\text{-}O_2\text{-}O_3)$	
	$(O_1\text{-}O_2)$	<	$(O_1\text{-}O_2\text{-}O_3)$	← 15 Subjects

X1 = Unaltered Laerdal Mannequin
X2 = Altered Laerdal Mannequin

O1 = Self assessment of force made by subject
O2 = Assessment of force made by observer
O3 = Maximum force recorded by sensors within mannequin

Figure 18. Schematic Representation of Phase One

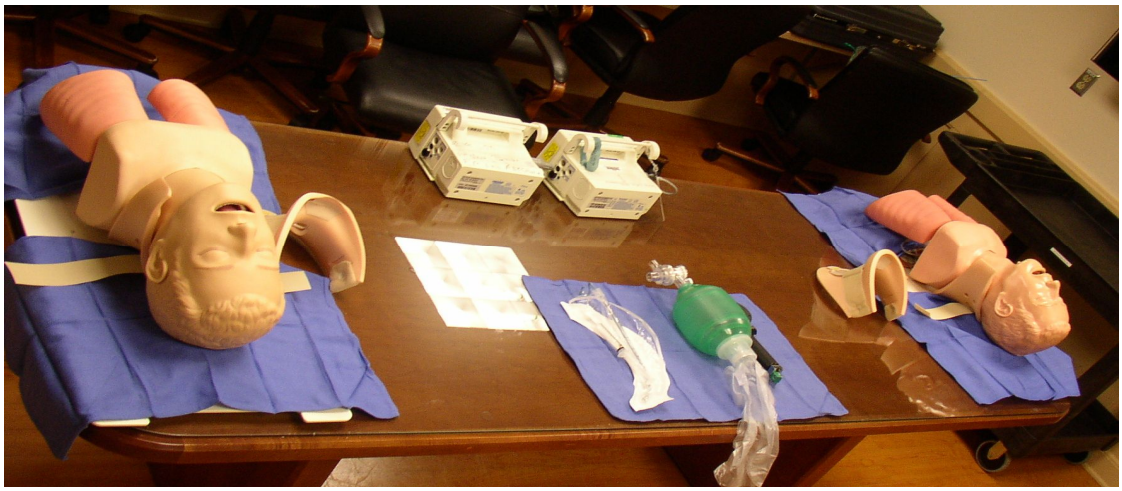


Figure 19. Image of Phase One

Demographic data regarding subjects for phase one can be seen in Table 1. Table 1 demonstrates a sixty percent CRNA participation. Approximately twenty percent participation by MDAs and twenty percent by Residents are also noted. Tabulated data of the perceived forces for phase one of this research is presented in Tables 2, and 3. Comparison of table 2 and 3 demonstrates an overall agreement that the research mannequin required significantly more force to intubate then the unaltered mannequin. This would be consistent with the intended modifications made to the research mannequin. Univariate statistics are shown in Table 4.

Table 1. Overall Provider Type

Provider Type	Frequency	Percent
CRNA	19	63
MDA	5	17
Residents	6	20
Total	30	100

Table 2. Descriptive Statistics for Categorical Pressure Data Unaltered Mannequin

	Unaltered Mannequin			
	Subjects Observations		Observer Observations	
Amount of Force	Frequency	Percent	Frequency	Percent
Min	17	56.7	19	63.3
Mod	11	36.7	9	30
Sig	2	6.7	2	6.7
Total	30	100	30	100

Table 3. Descriptive Statistics for Categorical Pressure Data Research Mannequin

	Research Mannequin			
	Subjects Observations		Observer Observations	
Amount of Force	Frequency	Percent	Frequency	Percent
Min	0	0	0	0
Mod	6	20	6	20
Sig	24	80	24	80
Total	30	100	30	100

Table 4. Univariate Statistics

Statistics	Unaltered Mannequin		Research Mannequin		
N=30	Subject	Observer	Subject	Observer	Pressure
Mean					177.4
Range					164
Minimum					125
Maximum					289
Std. Deviation	0.630	0.626	0.407	0.407	38.699
Skewness	0.888	1.172	-1.580	-1.580	0.682
Std. Error of Skewness	0.427	0.427	0.427	0.427	0.427
Kurtosis	-0.134	0.431	0.527	0.527	0.656
Std. Error of Kurtosis	0.833	0.833	0.833	0.833	0.833
Z skew	2.079	2.744	**-3.701**	**-3.701**	1.597
Z kurt	-0.161	0.517	**0.633**	**0.633**	0.788

Information found in Table 4 demonstrates a large negative skew, standard skew = -1.580 Z score = -3.701, occurring for observations made by both the subjects and the observer during intubation of the research mannequin. Variables with a standard skew Z score of greater than 3.3 suggests with 99% confidence that the sample does not represent a normal population. Data displayed in Table 4 would indicate that the reason for this

skew is that all subjects and observers scored either moderate or significant force, 20% and 80% respectively, while minimal force received no scores. For this reason, the variable was transformed into a binary variable of moderate or significant, correlating to the 20% and 80% respectively. This would allow for the continued use of the variable as a binary on the bases that there was at least 10% of the sample in each cell within the dataset.

Correlation analysis on the data generated from the phase one component of the research is shown in Table 5. Table 5 demonstrates that observer and subject observations of pressure were found to be significantly correlated, $r = .743$, $p < 0.001$, when rating the intubation force on the unaltered mannequin. Observer and subject observations were found to have an extremely high degree of correlation, $r = 1.0$ $p = 0.001$, when rating the intubation force on the research mannequin. This would indicate that a high degree of agreement in terms of perceived force exists between both, the ratings of the subject performing the intubation and the ratings of an observer of the intubation. This was true for both the altered and unaltered mannequin.

No statistically significant correlation was found in terms of perceived force made by either the ratings of the subject performing the intubation, or the ratings of an observer of the intubation, to the categorical pressure observations recorded by the research mannequin.

Table 5. Correlation Analysis for Phase One

Correlations (N=30)		Unaltered Mannequin		Research Mannequin		
		Subject	Observer	Subject	Observer	Pressure
Unaltered Mannequin Subject	Pearson Correlation	1	**0.743****	0.134	0.135	**-0.454***
	Sig. (2-tailed)		0	0.478	0.478	**0.012**
Unaltered Mannequin Observer	Pearson Correlation	**0.743****	1	-0.054	-0.054	-0.268
	Sig. (2-tailed)	**0**		0.776	0.776	0.152
Research Mannequin Subject	Pearson Correlation	0.134	-0.054	1	**1****	0.093
	Sig. (2-tailed)	0.478	0.776		**0**	0.625
Research Mannequin Observer	Pearson Correlation	0.134	-0.054	**1****	1	0.093
	Sig. (2-tailed)	0.478	0.776	**0**		0.625
Research Mannequin Pressure	Pearson Correlation	**-0.454***	-0.267	0.093	0.093	1
	Sig. (2-tailed)	**0.012**	0.152	0.625	0.625	

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

The information in Table 5. would indicate that no agreement was present between the pressures, as measured by the research mannequin and then converted into categorical data, and the amount of perceived force made by the subject and the observer. Based on this finding, no support in terms of the validity of either measurement can be made. This is due to the lack of any standard benchmark that would allow for comparison and validation of either the perceptions of the subjects and observers or the mannequin. For these reasons, the lack of agreement is not perceived as being a fatal finding in terms of the design and performance of the research mannequin. Rather, it is perceived as a starting point for further examination. There appears to be no correlation between quantitative measurements obtained by the research mannequin and those perceived by either the observer or the person performing the intubation.

Data generated by phase one of this research was also assessed as originally proposed using Cohen's kappa statistical technique. Pressure data was divided into three groups corresponding to minimum, moderate, and significant. Due to the presence of the negative skew within the pressure data, two methods of categorizing this information were performed and tested separately. The first method was to divide the distribution of pressure readings at the 33 and 66 percentiles using a range beginning with zero and ending with the highest pressure value obtained, of 289 mm Hg. The second method of data division was to divide only the range of pressure, 125 – 289 mm Hg, into two categories, moderate and significant. This second method was an attempt to superimpose normality on the data by recognizing the binary nature of this variable. Results, along with their interpretations using Landis and Koch's table of kappa values are shown in Table 6. (Landis and Koch 1977).

Table 6. Kappa Analysis for Phase One Data

Research Mannequin			
Measure of Agreement	Kappa	Significance	Kappa Interpretation
Between Subjects and Observer	1	.000	Perfect Agreement
Method One (0-289)			
Between Subjects and Pressure (0-289)	0.167	0.192	Slight Agreement
Between Observer and Pressure (0-289)	0.167	0.192	Slight Agreement
Method Two (125-289)			
Between Subjects and Pressure (125-289)	0.020	0.819	Slight Agreement
Between Observer and Pressure (125-289)	0.020	0.819	Slight Agreement

The findings using Cohen's kappa analysis were consistent with the correlation analysis previously performed and does not present any new information but are presented here for completeness.

Summary of Phase One.

In summary, phase one of this research was undertaken in part to compare the research model against an unaltered Laerdal mannequin. This comparison was made of the ability of the research model to better simulate the difficulty of airway management of a patient with a compromising cervical spinal injury. The ability of the research mannequin to do so would appear to be supported by the data generated during the first phase of this study. Evidence of this finding is supported by the consistent scoring of the research mannequin requiring more force to intubate then the standard mannequin as perceived by both the subjects and observer. Additionally phase one had the purpose of piloting the performance of the mannequin in a research setting. No difference between the unaltered mannequin and the research mannequin was noted by the subjects and the observer other then the degree of difficulty to intubate as previously stated.

No correlation between the perceptions of the degree of force made by either the observer or the subjects and the pressure measurement made by the research mannequin were demonstrated. This disconnect may reflect the difficulty in converting the variable of continuous pressure measurements made by the research mannequin into categorical data. This finding also calls into question the validity of the mannequin's ability to reflect accurately the differences in the degree of pressure within a single technique. Due to the lack of a standard measurement for the forces experienced during intubation, no definitive comparison has yet to be developed.

Main Study Design

This portion of the study design is a prospective analysis used to assess variability over six airway devices, three provider types, and five data collection locations. A multivariate profile analysis using a covariate of experience of subjects was performed. A multivariate analysis of covariance (MANCOVA) was the proposed statistical design. Six airway management techniques were tested. Each was selected based on their consistent appearance within the clinical anesthesia literature. The techniques to be tested were trans-tracheal illumination using the Trachlight®, direct laryngoscopy, using both the Miller 3 and the Macintosh 3 blades, indirect laryngoscopy, using the C-Mac video laryngoscope with the #3 blade (C-Mac 3), a flexible fiberoptic bronchoscope (FOI), and finally the supraglottic Fastrach™ Intubating Laryngeal Mask Airway (FTLMA). Although there are a large number of specific devices and techniques marketed for airway management, the six devices selected for this study represent commonly used methods found in clinical practice and therefore allow for the greatest generalization of the study results.

Data Collection

After obtaining approval from the Virginia Commonwealth University Institutional Review Board, data collection took place during the Airway Management Education Center's (AMEC) difficult airway courses. AMEC is a specialized healthcare education company primarily focused on high-quality airway management instruction throughout the country. This group runs a minimum of five courses across the United States each year. Data was collected for this research at the following five locations and

are presented in chronological order of collection: Chicago, Atlanta, Las Vegas, Seattle, and Boston. Approximately 100 anesthesia providers and 100 emergency medical professionals attended each course. Attendees were recruited on a volunteer basis. It should be recognized that the population from which the subjects were recruited is one of self-selection in that only providers attending a class in airway management could participate in this study. This may represent a potential difference between the sampling population and the greater population of airway providers.

It was the original intention of this research to stratify the recruitment of the subjects in both terms of provider type and the course-day on which the individual was recruited. It was realized at the first data collection location that this was an unrealistic goal and would not be achievable. The reason for the inability to stratify subjects in terms of course day was the lack of the availability of equipment for each of the three days of the course. The ability to have the same six devices available for research purposes was only logistically possible for the last half of course day one and all of day two. This inequity in terms of course day also had ramifications for the stratification of provider type. It was decided that in order to maximize the number of subjects enrolled in the research, and hence maximize the power and ability to generalize the data results of the study, course day would be dropped as a covariate and any subjects willing to participate during the time that all six devices were available would be allowed.

All subjects were recruited by convenience sampling from three cohorts; the first cohort was physicians practicing in the field of emergency medicine (MDEM). The inclusion of emergency medicine physicians as a provider type for this research was

undertaken in order to expand the research beyond that of only anesthesia providers and allow for greater meaning of the results. The second cohort consisted of certified registered nurse anesthetists (CRNA). The third cohort consisted of physician anesthesiologists (MDA). The three-provider types represent the vast majority of individuals providing clinical airway management within the United States healthcare system. The combination of providers found at the five courses should reflect the care provided across the large spectrum of patients being managed with spinal immobilization. This cross sectional analysis will provide information regarding forces applied by practitioners due to differing skill levels, geographical location, familiarity with differing airway techniques and any associated contributions based on practitioner types.

The number of subjects originally proposed was nine from each of the three provider types, totaling 27 subjects from each course location and 135 subjects total for the study. This stratification plan was abandoned at the first data collection location for reasons previously mentioned above. The proposed 135 subjects-number was reached by assigning an effect size of 0.25. This effect size would explain 25% of the variability and was selected in order to reflect a balance between a small and moderate effect having relevance to the clinical situation. In reviewing the literature regarding spinal movement during intubation, no agreed upon acceptable level of movement has been reached. Due to the coupling of force and movement, this is also true of mechanical force. For this reason, the spine of the research mannequin was completely immobilized, thus eliminating this source of variability due to movement. While no acceptable level of force has been agreed upon, a small to moderate difference between techniques could prove to

be relevant in the clinical setting. An a priori determination of required sample size using G-Power software (Faul, Erdfelder, Lang & Buchner 2007) demonstrated the following: with an alpha of p=0.05 and a power of 0.8 (1-β error probability), 45 subjects per group would sufficiently power the study with a predetermined small to moderate effect size. Therefore, a final aggregate of 135 subjects was proposed. Unfortunately, only 102 subjects were actually studied for reasons elaborated upon in the previous text.

The research mannequin model was tested by examining the performance of three different groups of providers using six intubation techniques at five locations. Variables are listed below.

Variables

Techniques

1. Trachlight®
2. C-Mac 3 video laryngoscope
3. Flexible fiberoptic bronchoscope
4. Fastrach™ LMA
5. Standard laryngoscopy using a # 3 Miller blade
6. Standard laryngoscopy using a # 3 Macintosh blade

Practitioner Type

1. Emergency medicine physicians (MDEM)
2. Certified registered nurse anesthetists (CRNAs)
3. Anesthesiologists (MDAs)

Location

1. Chicago IL. 2. Las Vegas NV.

3. Atlanta GA. 4. Seattle WA.

5. Boston MA.

Co-Variables

1. Experience of the provider. Experience was measured in years of clinical airway practice. Post data collection this variable was transformed into the log of the years of experience of the provider.

2. The day of data collection, consisting of three groups: 1. Friday 2. Saturday 3. Sunday.

This co-variable was originally proposed but dropped from the research design due to logistical complications of equipment availability explained previously.

Dependent Variables

1. Maximum pressure exerted.
2. Time to ETT placement.

The mannequin was prepared as described above. Immediately prior to beginning each new subject, the mannequin's pressure transducers was recalibrated to zero. The mannequin was held in place on a standard worktable and was affixed to the table using two six-inch C-clamps. The mannequin was placed in a cervical collar with the front section removed in order to simulate the intubation of the spinal immobilized patient. Each subject was told that the nature of the experiment was to assess the mannequin for future teaching of airway management regarding the spinal immobilized patient relative

to force and intubation. Subjects performed intubations using each of the six techniques and a 7.0-millimeter internal diameter ETT. Each subject was asked to perform the intubation in a manner consistent with the management of a spinal injured patient. Maximum pressure readings obtained during the intubation attempt were documented.

Preliminary Data Assessment

The main portion of this research was originally to consist of a multivariate profile analysis with covariate of experience using a MANCOVA approach. Testing of six different airway devices, used by three types of airway providers, at five locations across the country, all using a single research model was undertaken. A schematic representation of the proposed research can be seen in Figure 20. As stated previously, it was the original intention of this research to stratify the recruitment of the subjects in both terms of provider type and the course-day on which the individual was recruited. This was not possible for reasons previously described. All subjects willing to participate during the time that all six devices were available were included in the research. This resulted in the overall recruitment of 102 subjects.

Frequencies of the three provider types broken down across the five locations are shown in Figure 21. Figure 21 demonstrates that nearly 50% of the participants of this research were certified registered nurse anesthetists, followed by emergency medicine physicians at 30%, and anesthesiologists at 20%. The ratio of participation was roughly consistent across all five locations and seemed to support the ability to generalize the results to the larger population of airway care providers.

L_1		X_1	X_2	X_3	X_4	X_5	X_6
	S_1 (1-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_2 (1-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_3 (1-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
L_2		X_1	X_2	X_3	X_4	X_5	X_6
	S_1 (11-20)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_2 (11-20)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_3 (11-20)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
L_3		X_1	X_2	X_3	X_4	X_5	X_6
	S_1 (21-30)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_2 (21-30)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_3 (21-30)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
L_4		X_1	X_2	X_3	X_4	X_5	X_6
	S_1 (31-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_2 (31-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_3 (31-10)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
L_5		X_1	X_2	X_3	X_4	X_5	X_6
	S_1 (41-50)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_2 (41-50)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)
	S_3 (41-50)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)	(O_1-O_2)

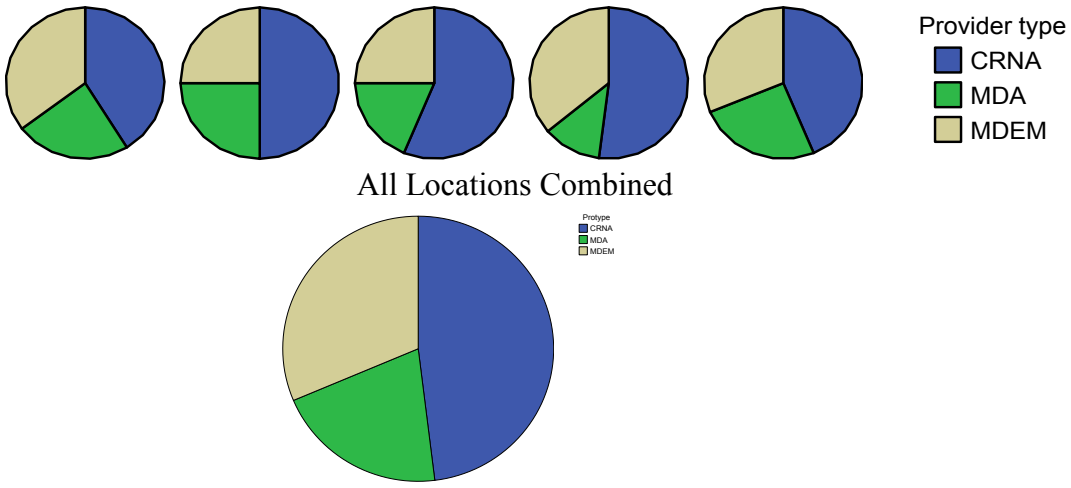
X1 = Trachlight®
X2 = C-Mac 3 video laryngoscope
X3 = Flexible fiberoptic bronchoscope
X4 = Standard laryngoscopy using a # 3 Miller blade
X5 = Fastrach™ LMA
X6 = Standard laryngoscopy using a #3 Macintosh blade

O1 = Maximum force recorded by mannequin sensors
O2 = Time taken to place ETT

S1 = Emergency medicine physicians (MDEMs)
S2 = Certified registered nurse anesthetist(CRNA)
S3 = Anesthesiologists (MDAs)

L1 = Chicago Ill.
L2 = Las Vegas NV.
L3 = Atlanta GA
L4 = Seattle WA
L5 = Boston MA.

Figure 20. Schematic Representation of Main Study



		Location					Total	
		Chicago	Las Vegas	Atlanta	Seattle	Boston		Percent
Provider	CRNA	7	6	9	13	14	49	48%
	MDA	4	3	3	3	8	21	21%
	MDEM	6	3	4	9	10	32	31%
Total		17	12	16	25	32	102	
Percent		17%	12%	16%	24%	31%		

Figure 21. Frequencies of Provider Types by Locations

Accuracy and Data Assessment

Accuracy of data entry was assessed by entering the data from the raw data collection forms twice and comparing the two datasets. Once the two datasets were found to be identical, it was assumed that no data entry omissions or errors were made.

No missing data was found when the dataset was examined. The failure rate for each device for 102 subjects attempting intubation is shown in Table 7. Failed intubation was defined as the subject stating that successful intubation would be unlikely and they would stop and attempt a different technique or device. Direct laryngoscopy with a three Miller and a three Macintosh blade demonstrated a 29% and a 21% failure rate, respectively.

Table 7. Failure Rate for Techniques

	Mac 3	Mil 3	FOI	FTLMA	C-Mac 3	Trachlight®
# Successful	72	81	100	100	102	102
# Failed	30	21	2	2	0	0
% Failed Rate	29%	21%	2%	2%	0	0

The high rate of failure for both techniques of direct laryngoscopy using the three Miller and the three Macintosh blades presented a problem. This high failure rate would reduce the sample size at a minimum from 102 to 72, the number of failures for the Macintosh 3 intubation technique. This number would most likely be higher due to the lack of complete overlap of the two variables. For this reason, a preliminary statistical analysis of the model was performed both with and without the inclusion of pressure data obtained from the Macintosh 3, and Miller 3 techniques.

Pressure scores and the covariate experience were assessed for extreme values, univariate outliers, and normality. Variables with a standard skew greater than 3.3 suggested with 99% confidence that the sample does not represent a normally distributed population. Table 8 contains univariate statistics for the dataset and demonstrates a large skew as defined by a standard skew greater than 3.3, for the following variables: Experience, Fiberoptic Intubation, Fastrach-LMA, and the Trachlight®.

Table 8. Univariate Statistics

	Exper	Mac 3	Mil 3	FOI	FT-LMA	C-Mac	Trachlight®
Successful	102	72	81	100	100	102	102
Mean	6.95	190.82	200.38	18.88	62.5	114.71	44.41
Std. Deviation	5.13	42.66	35.59	10.94	22.24	32.8	15.67
Skewness	1.24	0.36	0.37	1.24	1.06	0.67	0.95
Error of Skew	0.24	0.28	0.27	0.24	0.24	0.24	0.23
Kurtosis	0.79	0.039	0.68	2.69	0.76	0.45	2.79
Error of Kurtosis	0.47	0.56	0.53	0.48	0.48	0.47	0.47
Minimum	1	104	108	2	24	46	10
Maximum	23	288	291	64	136	217	106
Standard Skew	**5.17**	1.27	1.39	**5.13**	**4.39**	2.81	**3.97**
Standard Kurtosis	1.66	0.069	1.28	**5.63**	1.58	0.95	**5.90**

In the case of the variable experience, an understandable positive skew was present. This represents a clustering for years of experience of subjects ranging from one to ten years, with a positive tail out to 23 years of experience. Logarithmic transformation, a standard statistical approach to normalizing a skewed variable (Tabachnick, & Fidell, 2007), was applied to the variable experience. The transformation resulted in a standard skew of -0.667, more consistent with a normal distribution probably present in a diverse population of clinicians providing advanced airway management. Skew present in the other variables was suspected to be due to the effects of outliers, discussed below and were addressed as such.

Univariate outliers were examined using scatter plots. Multivariate outliers were identified using Mahalanobis distance of each case to the centroid of all cases. The ten cases with the largest Mahalanobis distance can be observed in Table 9.

Table 9. Mahalanobis Distance for Multivariate Outliers

		Case Number	Statistic
Mahal. Distance	1	24	30.318
	2	74	23.639
	3	72	17.821
	4	5	16.981
	5	15	14.978
	6	25	14.594
	7	40	14.091
	8	41	13.818
	9	16	11.969
	10	42	11.866

Because Mahalanobis distance is distributed as a chi-square variable, the critical chi-square at the desired alpha level, in this case 0.001 for 10 degrees of freedom, is 29.588. Therefore, any case with a value larger than 29.588 was considered a multivariate outlier. Only the first of the 10 cases, case number 24, was found to have a value greater than 29.588 and was therefore treated as a multivariate outlier.

In an effort to maximize the amount of usable data for analysis, mean substitution was used in dealing with outliers within the dataset. This was undertaken in the hope of producing meaningful results representative of the population of interest as well as maintaining consistency throughout data handling. The statistical mean was calculated with the inclusion of the outliers. This method of mean substitution allowed for the inclusion of the outliers effect on the mean to be retained in the final analysis, resulting in a dataset that minimized the effects of outliers but also retained the overall essence of the study results. The mean was substituted for the two failed cases of fiberoptic intubation as well as the two failed cases using the Fastrach LMA.

Information regarding the numbers of outliers for each technique is presented below. For the variable Trachlight®, five outliers were found and replaced by mean substitution. For the variable C-Mac 3, one outlier was found and replaced using mean substitution. For the variable Fastrach-LMA, six outliers were found. This combined with the two-failed intubation attempts referred to earlier resulted in an overall mean substitution of eight data points. For the variable Fiberoptic intubation, seven outliers were replaced. Combined with the two cases of failed intubation noted earlier nine data points in the variable were replaced with mean substitution.

Mean substitution was not used in the cases of failed intubation for the variables Macintosh 3 and Miller 3. This decision was based on the ability of the technique to alter the relationship among variables when a relatively large percentage of substitutions were made (Tabachnick, & Fidell, 2007). In this overall study, mean substitution was used in less than 3% of the data points used for data analysis.

Missing values analysis demonstrated a significant t-test for missing versus non-missing between the Mac 3 and the Mill 3, $t=2.7$, $df=45.2$, $p=.009$, and is based on 62 cases with 19 cases missing both. This missing data actually represents successful versus failed intubation for each of the two variables and is a significant finding in and of it self. How this finding impacts the data will be explored in the text below. No other patterns were found in relation to failed intubation or outliers.

Correlation analysis was next performed to assess for the presence of co-linearity and hence, redundancy among the variables. The results did demonstrate the presence of relationships at both $p< 0.05$ and $p< 0.001$ critical values. Although relationships were

demonstrated among several of the repeated measures and thus co-linear pressures suggest a similarity in use of the technique, none of these relationships rose to the degree of co-linearity. Therefore, all variables were retained for further analysis (See Table 10)

Table 10. Correlation Analysis of Variables

Correlations		Mac 3	Mil 3	Trachlight®	FTLMA	C-Mac	FOI
Mac 3	Pearson Correlation	1	**0.576**	-0.064	-0.046	**0.263**	0.113
	Sig. (2-tailed)		**0.00****	0.595	0.699	**.025***	0.346
Mil 3	Pearson Correlation	**0.576**	1	-0.027	0.027	-0.010	0.143
	Sig. (2-tailed)	**0.00****		0.813	0.809	0.931	0.204
Trachlight®	Pearson Correlation	-0.064	-0.027	1	0.030	-0.158	-0.139
	Sig. (2-tailed)	0.595	0.813		0.764	0.112	0.162
FT-LMA	Pearson Correlation	-0.046	0.027	0.030	1	0.165	**0.254**
	Sig. (2-tailed)	0.699	0.809	0.764		0.097	**.010***
C-Mac 3	Pearson Correlation	**0.263**	-0.010	-0.158	0.165	1	0.172
	Sig. (2-tailed)	**0.025***	0.931	0.112	0.097		0.083
FOI	Pearson Correlation	0.113	0.143	-0.139	**0.254**	0.172	1
	Sig. (2-tailed)	0.346	0.204	0.162	**0.010***	0.083	

** Correlation is significant at the 0.01 level (2-tailed)
* Correlation is significant at the 0.05 level (2-tailed)

Examination of the data with respect to accuracy of entry, missing values, outliers, normality and co-linearity resulted in a usable dataset with an N of 102 for all variables with the exception of the Macintosh 3 blade, N = 72, and the Miller 3 blade, N = 81. With the above data cleaning complete, all issues regarding normality would appear to be addressed within the dataset as demonstrated in Table 11.

Time Required to Intubation

Once obtained, the data was analyzed from the perspective of time to intubation. Time to intubation, for this study, was defined as the time beginning with insertion of the device beyond the mannequin's incisors and ending with conformation by ventilation of the correct placement of the ETT in the mannequin's trachea

Table 11. Final Univariate Statistics

	LogExper	Mac3	Mil3	FOI	FTLMA	C-Mac	Trachlight®
Successful	102	72	81	102	102	102	102
Failed	0	30	21	0	0	0	0
Mean	0.73	190.82	200.38	16.96	59.90	113.68	42.93
Std. Deviation	0.34	42.66	35.59	7.45	17.60	31.16	11.89
Skewness	-0.16	0.36	0.37	-0.06	0.62	0.53	-0.08
Error of Skew	0.24	0.28	0.27	0.24	0.24	0.24	0.24
Kurtosis	-0.32	0.04	0.68	-0.63	-0.23	0.10	-0.15
Error of Kurtosis	0.47	0.56	0.53	0.47	0.47	0.47	0.47
Minimum	0	104	108	2	24	46	14
Maximum	1.36	288	291	34	102	198	72
Standard Skew	-0.667	1.286	1.37	-0.25	2.58	2.21	-0.34
Standard Kurtosis	-0.681	0.071	1.28	-1.34	-0.49	0.21	-0.32

. The definition was adopted in order to assess only the time required to use each device and not the intricacies associated with the knowledge of the setup and preparation for use of each device. The time required to secure ETT placement is significant in that timely airway management reduces patient risk for aspiration and hypoxia. The findings regarding intubation times for this study are displayed in an ascending order in Table 12.

Table 12. Time to Intubation

Time in Seconds			
	Minimum	Maximum	Mean
FTLMA	17.00	110.00	40.88
Trachlight®	14.00	90.00	42.82
Miller 3	20.00	90.00	44.19
C-Mac 3	10.00	150.00	45.41
Mac 3	23.00	118.00	45.93
FOI	15.00	120.00	56.67

Mean times for all six-airway devices varied between 41 seconds for the LMA Fastrach (FTLMA) to 57 seconds for fiberoptic intubation (FOI). This data demonstrates

a range of only 16 seconds separating the means of the fastest device from the slowest. Time-data broken down by provider type showed even less variation. Time for successful intubation assessed within provider types varied by no more then 8 seconds for each device and no more then 17 seconds within a provider group. This data can be seen in Table 13.

Table 13. Tine to Intubation by Provider

Time in Seconds							
Provider type		FTLMA	Trachligh®	Miller 3	C-Mac 3	Mac 3	FOI
CRNA	Mean	40.84	44.27	44.13	48	45.70	57.94
	N	49	49	38	49	37	48
MDA	Mean	38.65	42.05	43.61	42.81	44.08	50.48
	N	20	21	18	21	12	21
MDEM	Mean	42.39	41.12	44.72	43.16	47.26	58.90
	N	31	32	25	32	23	31
Total	Mean	40.88	42.82	44.20	45.41	45.93	56.67
	N	100	102	81	102	72	100

No further evaluation of the time data was made. This decision was based on the realization that even in the presence of a statistical significant finding, no meaningful clinical relevance could be inferred based on such a small variation in time. Although for this model, it can be stated that the type of technique, the location, and the provider were all clinically irrelevant in terms of time required to place the ETT. For this reason hypotheses 8-14 listed below in Figure 22, are found to have no meaning in terms of clinical significance. Therefore, all seven hypotheses referring to time were dropped from further analysis.

H_8 There will be a statistically significant difference in the time required for intubation for each of the six different techniques.

H_9 There will be a statistically significant difference in the time required for intubation for each of the three different practitioner types.

H_{10} There will be no statistically significant difference in the time required for intubation for each of the five locations of data collection.

H_{11}. There will be a statistically significant difference in the time required for intubation for each of the six different techniques by each of the three different practitioner types.

H_{12} There will be no statistically significant difference in the time required for intubation for each of the six different techniques by each of the five locations of data collection.

H_{13} There will be no statistically significant difference in the time required for intubation for each of the three different practitioner types by the five locations of data collection.

H_{14} There will be a statistically significant difference in the time required for intubation for each of the six different techniques by the three different practitioner types by the five locations of data collection.

Figure 22. Rejected Hypotheses Regarding Time

Preliminary Pressure Data Analysis

Multivariate profile analysis with covariate of experience using a MANCOVA approach was performed on six dependent measures of pressure: Standard laryngoscopy, using a #3 Macintosh blade (Mac 3) and a # 3 Miller blade (Mil 3), Fiberoptic intubation using a flexible fiberoptic bronchoscope (FOI), Fastrach™ Intubating Laryngeal Mask Airway (FTLMA), C-Mac video laryngoscope, using the #3 blade (C-Mac 3), and the Trachlight® (Trachlight®). Independent variables analyzed were practitioner types having three levels: emergency medicine physicians, (MDEM), certified registered nurse

anesthetists, (CRNA), anesthesiologists, (MDA) and locations having five levels: Chicago, Las Vegas, Atlanta, Seattle, and Boston. The addition of the covariate, experience of the provider in the form of the logarithmic conversion was also used in the model.

Statistical Package for the Social Sciences (SPSS) was used for data analysis. This analysis demonstrated the following results. Total N of 102 subjects was reduced to N = 62. This was due to the deletion of all subjects who failed to intubate using either the McIntosh 3 or the Miller 3 blades. All assumptions were met with the exception of a violation of sphericity. This assumption of sphericity is similar to the assumption of homogeneity of variance between groups. In this case, it means that the correlations among the cells formed by the IVs are different within the model. Mauchley's test statistic was found to be significant ($p<.000$), suggesting that the assumption of sphericity had not been met. While this assumption is critical for ANCOVA, MANCOVA is robust to violations of sphericity (O'Brien & Kaiser, 1985). For this reason, the violation of sphericity was noted but not considered relevant to these preliminary results.

The results of this multivariate profile analysis of the pressure score centroid can be seen in the summary in Table 14. The analysis included all six techniques as independent variables and resulted in the use of 62 cases having complete data. This reduction in case-numbers was due to the combined high failure rate of the Macintosh 3 and the Miller 3 blades and resulted in only 62 cases having complete data.

Table 14. Multivariate Profile Analysis

Summary Table							
Source	SS	df	MS	F	p	Eta	Partial Eta
Between Subjects Effects							
Error	50180.95	46	1090.89				
Experience	2330.36	1	2330.36	2.14	0.151	0.030	0.044
Provider	2139.32	2	1069.66	0.98	0.383	0.027	0.041
Location	**20615.91**	**4**	**5153.98**	**4.72**	**0.003**	**0.261**	**0.291**
Prov by Loc	3572.32	8	446.54	0.4	0.909	0.045	0.066
Total	78838.86	61					
Source	SS	df	MS	F	p	Eta	Partial Eta
Within Subjects Effects							
Error	133394.07	235	567.63				
Technique	**1318528.5**	**5**	**263705.7**	**464.57**	**0**	**0.873**	**0.908**
Prov by T	6658.36	10	665.84	1.17	0.31	0.004	0.048
Loc by T	**30619.78**	**20**	**1530.99**	**2.7**	**0**	**0.020**	**0.187**
Prov by Loc by T	20889.07	40	522.23	0.92	0.611	0.012	0.135
Total	1510089.78	310					

Results of this analysis demonstrated that the tests of between-subjects effects were found to be statistically significant for the variable location, (F=4.72, df=4, p<.003 with an effect size of Partial Eta-squared (η^2) = 0.291) suggesting that 26% of the between effect and 29% of the variance in pressure scores was due to differences in location.

The test of within subject effect for techniques was also found to be statistically significant (F=464.57 df=5, p=0.000 and an effect size of Partial Eta-squared (η^2) =0.908) suggesting that 87% of the within effect and 91% of the variance in pressure scores was due to differences in the technique.

The test of within subject effect for location by techniques was found to be statistically significant, (F=2.7, df=20, p=0.000 and an effect size of Partial Eta-squared (η^2) = 0.187), suggesting that 25% of the within effect and 19% of the variance in pressure scores was due to differences in the interaction of location by technique.

Post-hoc power analysis for the significant findings stated above was assessed using the online free statistical calculators by D. S. Soper, and can be seen in Table 15 (Soper. 2010).

Table 15. Power Analysis

Post-Hoc Power Analysis		
6 Techniques		
3 Provider Types		N = 62
5 Locations		P = 0.05
	Effect Size	Power
Tech	0.908	1.000
Loc	0.291	0.976
Loc by Tech	0.187	0.661

Based on the large reduction in case numbers from 102 down to 62, and the over all implications this would have on the low power of detecting the Loc by Tech interaction in the statistical design, it was decided that the variables Mac 3 and Mil 3 would be removed from the final analysis and assessed separately in future analysis. This reduction in case usage was due to the high frequency of failed intubations for the two variables Mac 3 and Mil 3. The variables Mac 3 and Mil 3 would be removed from the final analysis. This separation of variables would allow for the assessment of the remaining four techniques in the same way as above, only with the inclusion of 102 cases rather then 62 cases. It was also the hope that the increase in N from 62 to 102 would

provide for a larger post-hoc power, reducing the possibility of a type II error and representing the overall populations of interest with greater accuracy.

Final Data Analysis for Chapter Four

Multivariate profile analysis with covariate of experience using a MANCOVA approach is the final statistical design. This analysis will be presented in Chapter Four and will consist of dependent measures of pressure for the following four techniques: Fiberoptic intubation using a flexible fiberoptic bronchoscope (FOI), the super-glottic device Fastrach™ Intubating Laryngeal Mask Airway (FTLMA), C-Mac video laryngoscope using the #3 blade (C-Mac 3), and the trans tracheal illumination device, the Trachlight® (Trachlight®). Independent variables analyzed will be practitioner types having three levels: emergency medicine physicians, (MDEM), certified registered nurse anesthetists, (CRNA), anesthesiologists (MDA), and locations having five levels: Chicago, Las Vegas, Atlanta, Seattle, and Boston.

Final Hypotheses

Hypothesis 1. There will be a statistically significant difference in mean maximum pressure for each of the six different techniques.

Hypothesis 2. There will be a statistically significant difference in mean maximum pressure for each of the three different practitioner types.

Hypothesis 3. There will be no statistically significant difference in mean maximum pressure for each of the five locations of data collection.

Hypothesis 4. There will be a statistically significant difference in mean maximum pressure for each of the six different techniques by each of the three different practitioner types.

Hypothesis 5. There will be no statistically significant difference in mean maximum pressure for each of the six different techniques by each of the five locations of data collection.

Hypothesis 6. There will be no statistically significant difference in mean maximum pressure for each of the three different practitioner types by the five locations of data collection.

Hypothesis 7. There will be a statistically significant difference in mean maximum pressure for each of the six different techniques by the three different practitioner types by the five locations of data collection.

For individual and group comparisons, a pre-study alpha of $p < 0.05$ was established as the determinant of statistical significance. This would provide a 95% confidence that a type I error was not included in the study results.

The above analyses will be explored in Chapter Four. A final schematic representation can be seen in Figure 23.

L_1		X_1	X_2	X_3	X_4
	S_1 (n=?)	O_1	O_1	O_1	O_1
	S_2 (n=?)	O_1	O_1	O_1	O_1
	S_3 (n=?)	O_1	O_1	O_1	O_1
L_2		X_1	X_2	X_3	X_4
	S_1 (n=?)	O_1	O_1	O_1	O_1
	S_2 (n=?)	O_1	O_1	O_1	O_1
	S_3 (n=?)	O_1	O_1	O_1	O_1
L_3		X_1	X_2	X_3	X_4
	S_1 (n=?)	O_1	O_1	O_1	O_1
	S_2 (n=?)	O_1	O_1	O_1	O_1
	S_3 (n=?)	O_1	O_1	O_1	O_1
L_4		X_1	X_2	X_3	X_4
	S_1 (n=?)	O_1	O_1	O_1	O_1
	S_2 (n=?)	O_1	O_1	O_1	O_1
	S_3 (n=?)	O_1	O_1	O_1	O_1
L_5		X_1	X_2	X_3	X_4
	S_1 (n=?)	O_1	O_1	O_1	O_1
	S_2 (n=?)	O_1	O_1	O_1	O_1
	S_3 (n=?)	O_1	O_1	O_1	O_1

X1 = Trachlight®
X2 = C-Mac 3 video laryngoscope
X3 = Flexible fiberoptic bronchoscope
X4 = Fastrach™ LMA

S1 = Emergency medicine physicians (MDEMs)
S2 = Certified registered nurse anesthetist(CRNA)
S3 = Anesthesiologists (MDAs)

L1 = Chicago Ill.
L2 = Las Vegas NV.
L3 = Atlanta GA
L4 = Seattle WA
L5 = Boston MA.

O1 = Maximum force recorded by mannequin sensors
O2 = Time taken to place ETT

Figure 23 Final Schematic Main Study

CHAPTER FOUR

As discussed previously, the purpose of this study was to develop and assess the reliability and validity of an experimental Model that allows for a single, multi-device, multi-provider, assessment of pressure and thereby, forces of airway management. The foundation of this research was the creation of a means of quantifying the amount of force experienced by a patient during airway management. By creating a mannequin that serves as the measuring tool rather than instrumenting the devices used to manage the airway, the ability to make cross comparisons of devices as well as other variables can be quantified and reproduced.

A review of the study objectives, research questions, and hypotheses are presented here.

Objectives

1. To develop an intubation model with the means of quantifying the forces experienced by a patient undergoing the placement of an endotracheal tube.
2. To develop an intubation model that simulates the difficulty commonly encountered in spinal immobilized patients

To then test the experimental model in varying geographical locations with differing clinical providers using a variety of airway management techniques and in that process, assess the validity and reliability of the model.

Operational Research Questions

The operational research questions of this study are:

Is there a statistically significant difference in maximum pressure required for intubation between:

1. Four different airway techniques.
2. Three different clinical practitioner types.
3. Five different geographical locations.
4. The interactions of the four techniques by the three practitioners.
5. The interactions of the four techniques by the five locations.
6. The interactions of the three practitioners by the five locations.
7. The interactions of the four techniques by the three practitioners by the five locations.

Hypotheses

Hypothesis 1. There will be a statistically significant difference in mean maximum pressure for each of the six different techniques.

Hypothesis 2. There will be a statistically significant difference in mean maximum pressure for each of the three different practitioner types.

Hypothesis 3. There will be no statistically significant difference in mean maximum pressure for each of the five locations of data collection.

Hypothesis 4. There will be a statistically significant difference in mean maximum pressure for each of the six different techniques by each of the three different practitioner types.

Hypothesis 5. There will be no statistically significant difference in mean maximum pressure for each of the six different techniques by each of the five locations of data collection.

Hypothesis 6. There will be no statistically significant difference in mean maximum pressure for each of the three different practitioner types by the five locations of data collection.

Hypothesis 7. There will be a statistically significant difference in mean maximum pressure for each of the six different techniques by the three different practitioner types by the five locations of data collection.

For individual and group comparisons, a pre-study alpha of $p < 0.05$ was established as the determinant of statistical significance. This would provide a 95% confidence that a type I error was not included in the study results.

As stated in the previous chapters, the purpose of this study was to develop and establish the initial reliability and validity of the airway-training model, described in Chapter Three. This model will allow for a quantitative analysis of the forces that are expected to occur in a patient undergoing a wide realm of definitive airway management techniques and thus clarify large gaps in the literature.

Multivariate profile analysis with covariate of experience using a MANCOVA approach is presented here. This statistical design consists of dependent measures of pressure for the following four techniques: Fiberoptic intubation using a flexible fiberoptic bronchoscope (FOI), the super-glottic device Fastrach™ Intubating Laryngeal Mask Airway (FTLMA), C-Mac video laryngoscope using the #3 blade (C-Mac 3), and

the trans tracheal illumination device the Trachlight® (Trachlight®). Independent variables analyzed will be practitioner types having three levels: emergency medicine physicians, (MDEM), certified registered nurse anesthetists, (CRNA), anesthesiologists, (MDA) and locations having five levels: Chicago, Las Vegas, Atlanta, Seattle, and Boston. The schematic representation of analyses can be seen in Figure 24.

L_1		X_1	X_2	X_3	X_4
	S_1 (n=?)	O_1	O_1	O_1	O_1
	S_2 (n=?)	O_1	O_1	O_1	O_1
	S_3 (n=?)	O_1	O_1	O_1	O_1
L_2		X_1	X_2	X_3	X_4
	S_1 (n=?)	O_1	O_1	O_1	O_1
	S_2 (n=?)	O_1	O_1	O_1	O_1
	S_3 (n=?)	O_1	O_1	O_1	O_1
L_3		X_1	X_2	X_3	X_4
	S_1 (n=?)	O_1	O_1	O_1	O_1
	S_2 (n=?)	O_1	O_1	O_1	O_1
	S_3 (n=?)	O_1	O_1	O_1	O_1
L_4		X_1	X_2	X_3	X_4
	S_1 (n=?)	O_1	O_1	O_1	O_1
	S_2 (n=?)	O_1	O_1	O_1	O_1
	S_3 (n=?)	O_1	O_1	O_1	O_1
L_5		X_1	X_2	X_3	X_4
	S_1 (n=?)	O_1	O_1	O_1	O_1
	S_2 (n=?)	O_1	O_1	O_1	O_1
	S_3 (n=?)	O_1	O_1	O_1	O_1

O1 = Maximum force recorded by mannequin sensors

X1 = Trachlight®
X2 = C-Mac 3 video laryngoscope
X3 = Flexible fiberoptic bronchoscope
X4 = Fastrach™ LMA

S1 = Emergency medicine physicians (MDEMs)
S2 = Certified registered nurse anesthetists (CRNAs)
S3 = Anesthesiologists (MDAs)

L1 = Chicago Ill.
L2 = Las Vegas NV.
L3 = Atlanta GA
L4 = Seattle
L5 = Boston MA.

Figure 24 Schematic Representation of Analyses

Results

Outliers

Information regarding the numbers of outliers for each technique was presented in Chapter Three. Further information regarding the nature of several of these outliers I is presented here in Chapter Four. This was due to their potential impact on the development and overall evaluation of the research model.

For the variable Trachlight®, the two highest-pressure values obtained and identified as outliers had notations made by the observer. The observer noted that the subjects each had attempted to advance the endotracheal tube without complete retraction of the device's internal stylet. According to the manufacturer, this stylet should be retracted approximately 10 cm in order to reduce the risk of damage to the tracheal wall when the tube/Trachlight® is advanced into the trachea. Following this finding, the complete data for the variable Trachlight® was then reviewed for observer notations. No observer notations or similar breach in technique was documented for any other data points. This breach in technique was therefore detected by the research mannequin in the form of outliers, each having the two highest-pressure readings within the variable. This was perceived as an indication of the validity of the mannequin in that it was capable of generating legitimate pressure scores representing a breach in the technique.

For the variable fiberoptic intubation (FOI), seven outliers were identified. Surprisingly, all of the seven were the highest-pressure values obtained for the variable. For each of the seven outliers the observer noted that the subject had difficulty in advancing the endotracheal tube over the fiberoptic cable once the fiberoptic cable had

been placed in the trachea. The mechanism of this difficulty was assumed to be due to what is a well-described phenomenon in the literature. This type of difficulty has previously been reported and is well documented in clinical practice by Johnson et al (2005). According to Johnson et al. (2005), the difficulty encountered is the result of the interaction of the bevel of the endotracheal tube with the patient's arytenoid cartilage. This interaction was found to occur in up to 53% of first pass attempts of the endotracheal tube during awake-fiberoptic intubations. This seemed to indicate that the experimental model, the research mannequin, was capable of discerning the presence of two distinct populations within the dataset for the variable fiberoptic intubations (see Figure 25.). The first of the two populations would consist of those intubations that have no difficulty or interaction between the endotracheal tube and the patient's arytenoid cartilage. The second and smaller population can be defined as those intubations having difficulty advancing the endotracheal tube when interaction between the endotracheal tube and the patient's arytenoid cartilage occurs. This population is indicated by the arrow in Figure 25. The complete dataset for the variable fiberoptic intubation was reviewed in order to assess if this difficulty was seen in other than those cases identified as outliers. No difficulty in advancing the endotracheal tube was noted by the observer other than those already identified by the pressure scores obtained from the research mannequin and thought to be outliers. This was also perceived as an indication of the validity of the mannequin in that it was capable of detecting legitimate pressure scores representing clinically relevant events.

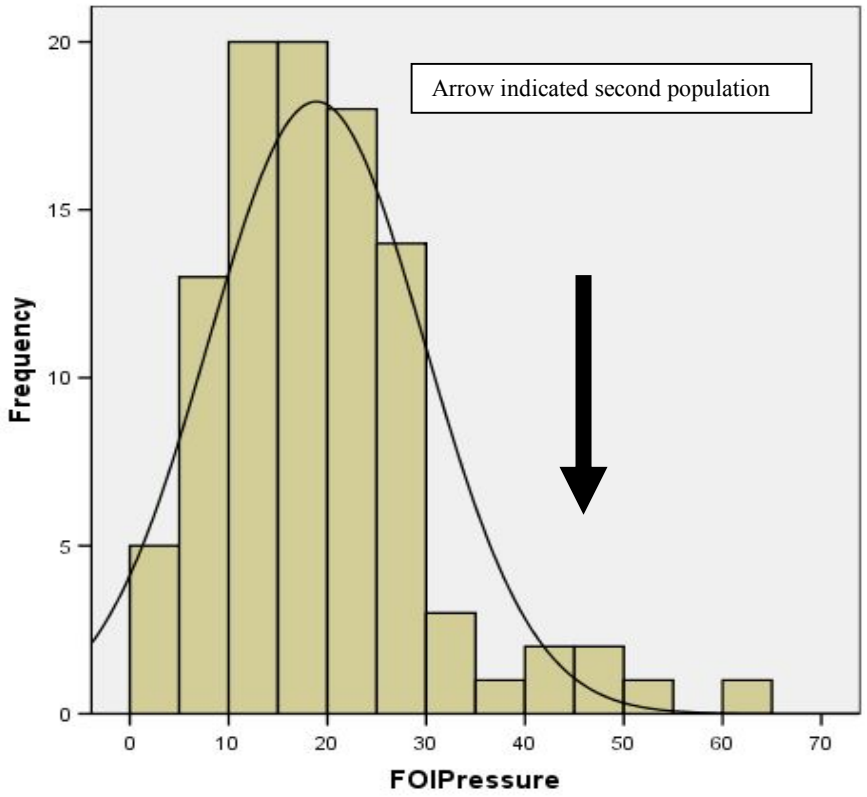


Figure 25. Bimodal Pressure Curve for FOI.

Statistical Results

Multivariate profile analysis with covariate of experience using a MANCOVA approach was performed on four dependent measures of pressure: Fiberoptic intubation using a flexible fiberoptic bronchoscope (FOI), Fastrach™ Intubating Laryngeal Mask Airway (FTLMA), C-Mac video laryngoscope using the #3 blade (C-Mac 3), and the Trachlight® (Trachlight®). Independent variables analyzed were practitioner types having three levels: emergency medicine physicians, (MDEM), certified registered nurse anesthetists, (CRNA), anesthesiologists, (MDA), and locations having five levels: Chicago, Las Vegas, Atlanta, Seattle, and Boston. The addition of the covariate,

experience of the provider in the form of the logarithmic conversion, was used in the model.

The software, Statistical Package for the Social Sciences (SPSS) was used to analyze the data. Descriptive statistics for the variables can be seen in Table 16 and 17 below.

Table 16. Descriptive Statistics

	LogExper	FOI	FT-LMA	C-Mac 3	Trachlight®
N	102	102	102	102	102
Mean	0.73	16.96	59.90	113.68	42.93
Std. Deviation	0.34	7.45	17.60	31.16	11.89
Skewness	-0.16	-0.06	0.62	0.53	-0.08
Std. Error of Skewness	0.24	0.24	0.24	0.24	0.24
Kurtosis	-0.32	-0.63	-0.23	0.10	-0.15
Std. Error of Kurtosis	0.47	0.47	0.47	0.47	0.47
Minimum	0	2	24	46	14
Maximum	1.36	34	102	198	72
Standard Skew	-0.667	-0.25	2.58	2.21	-0.34
Standard Kurtosis	-0.681	-1.34	-0.49	0.21	-0.32

Table 17. Frequencies of Provider Type by Location

		Location					Total	
		Chicago	Las Vegas	Atlanta	Seattle	Boston		Percent
Provider	CRNA	7	6	9	13	14	49	48%
	MDA	4	3	3	3	8	21	21%
	MDEM	6	3	4	9	10	32	31%
Total		17	12	16	25	32	102	
Percent		17%	12%	16%	24%	31%		

Frequencies of the three provider types broken down across the five locations are shown in Table 17. As reported in Chapter Three, 48% of the participants of this research were certified registered nurse anesthetists, followed by emergency medicine

physicians at 31%, and anesthesiologists at 21%. The ratio of participation was roughly consistent across all five locations and seemed to support the ability to generalize the results to the larger population of airway care providers.

A total N of 102 subjects was achieved. All assumptions were met with the exception of a violation of sphericity. This assumption of sphericity is similar to the assumption of homogeneity of variance between groups. In this case, it means that the correlations among the cells formed by the IVs were different within the model. Mauchley's test statistic was significant ($p<.000$), suggesting that the assumption of sphericity had not been met. While this assumption is critical for ANCOVA, MANCOVA is robust to violations of sphericity (O'Brien & Kaiser, 1985). For this reason, the violation of sphericity is noted and will be considered in results interpretation. The results of the multivariate profile analysis with the covariate of experience are presented in the summary in Table 18. The analysis included four techniques and resulted in the use of 102 cases having complete data.

For this analysis, no between subjects effects were found to be statistically significant. This was not the case for the test of within subjects. The within subjects effect for techniques was found to be statistically significant ($F=373.97$ df =3, $p=0.000$ and an effect size of Eta =0.784 and Partial Eta (η^2) = 0.811). This would suggest that 78% of the within effect and 81% of the variance in pressure scores was due to differences in technique. Table 19 shows the means and the standard deviations for the four techniques.

Table 18. Multivariate Profile Analysis

Source	SS	df	MS	F	p	Eta	Partial Eta
Between Subjects Effects							
Error	37001.35	86	430.25				
Experience	0.17	1	0.17	0	0.984	.000	.000
Provider	127.89	2	63.95	0.15	0.862	0.003	0.003
Location	3940.31	4	985.08	2.29	0.066	0.090	0.096
Prov by Loc	2640.13	8	330.02	0.77	0.633	0.060	0.065
Total	43709.85	101					
Source	SS	df	MS	F	p	Eta	Partial Eta
Within Subjects Effects							
Error	89043.12	261	341.16				
Technique	**382750.94**	**3**	**127583.7**	**373.97**	**0**	**0.784**	**0.811**
Prov by T	1395.86	6	232.64	0.68	0.664	0.003	0.015
Loc by T	**8052.62**	**12**	**671.05**	**1.97**	**0.028**	**0.016**	**0.083**
Prov by Loc by T	6979.65	24	290.82	0.85	0.667	0.014	0.073
Total	488222.19	306					

Table 19. Pressure Scores for the Four Techniques

	C-Mac 3	FT-LMA	Trachlight®	FOI
N	102	102	102	102
Mean	113.68	59.90	42.93	16.96
Std. Deviation	31.16	17.60	11.89	7.45

The test of within subjects effect for location by techniques was also found to be statistically significant, (F=1.97, df =12, p=0.028 and an effect size of Eta = 0.016 and a Partial Eta (η^2) = 0.082). This suggests that 2% of the within effect and 8% of the variance in pressure scores was due to differences in the interaction of location by technique.

Simple effects testing on the technique by location effect are displayed in Table 20 and demonstrate a consistent statistically significant finding of technique across all

five locations with small variation in Partial eta. This means that the technique differences from city to city varied minimally, with differences in pressure variance explained at 78.3% to 80.1%, less than a 3% difference between cities. This small difference in variation over the five data collection locations seemed to support the reliability of the experimental mannequins function over both time and location.

Table 20. Simple Effect for Technique

	SS	F	df	p	Eta	Partial Eta
Chicago	85515.71	57.76	3	0	0.801	0.805
Las Vegas	57083.14	62.37	3	0	0.864	0.874
Atlanta	73609.59	104.54	3	0	0.868	0.889
Seattle	62153.56	128.57	3	0	0.834	0.854
Boston	158825.02	114.32	3	0	0.783	0.796

Table 21 displays pressure score means and standard deviations of each cell formed by simple contrasts. Table 22 displays the p values for these simple effects tests. The tests used are univariate ANOVA tests where the observed p value obtained and displayed in the table is compared against the Bonferroni p value of .083 to achieve 95% confidence. Because the overall interaction of location and technique explains less than 2% of the variance, and no clinical significance is apparent, statistical significance of simple contrasts was not performed.

Table 21. Techniques by Location

	Mean (SD)					
Chicago/17	40.88(14.4)	68.06(16.2)	116.88(36.6)	20.40(7.0)	61.55	11.46
Las Vegas/12	42.42(11.7)	61.08(19.8)	115.75(23.5)	17.06(6.6)	59.07	8.74
Atlanta/16	41.06(15.9)	68.75(10.6)	120.94(23.9)	20.38(7.0)	61.65	10.76
Seattle/25	45.48(10.1)	60.89(12.9)	103.72(20.5)	15.04(7.2)	57.6	8.51
Boston/32	43.16(9.8)	66.32(15.3)	115.34(39.5)	14.88(7.5)	55.32	10.63
Total/102	42.93(11.9)	59.90(17.6)	113.68(31.2)	16.96(7.5)	58.36	10.23

Table 22 Simple Effect p Values

Technique/pvalue					
	Trachl/.985	FTLMA/.037	CMAC3/.151	FOI/.175	Total/.066

*Bonferroni Correction for p<.05 0.0083

Summary of Assessment

As previously stated, the total rows displayed are the means compared by the technique effect, F=373.97, df =3, p=.000, Eta =78.4%, Partial Eta =81.1%. Location by technique compares all 20 cell means, F=671.05, df=12, p=.028, Eta=1.6%, Partial Eta=8.2%. The total column is the means compared by the location effect, F=2.29, df =4, p=.066, Eta=9%, Partial Eta=9.6%. For the two variables, location, technique and their combination, only the variable technique was found to be statistically significant.

How these findings apply to the study hypotheses can be seen below:

Hypothesis 1. This hypothesis stated that there would be a statistically significant difference in mean maximum pressure for each of the four different techniques. It was supported by the findings with 81% of the variance in pressure scores attributed to differences in technique. This would suggest that 81% of the variance in the pressure experienced by a patient undergoing intubation could be manipulated simply by the choice of insertion technique that is selected, and would represent the ability to control a major portion of the force. A univariate post-hoc test of mean pressures for each of the four techniques was performed for the five locations. The results of this analysis can be seen in Table 23 and Figure 26. For the purposes of completeness in presenting the data, the techniques of Mac 3 (N=72) and Mil 3 (N=81) are included for comparison in Table 23 and Figure 27.

Table 23 Minimum, Maximum and Mean Pressures by Techniques

		Mean	Minimum	Maximum
Mill 3	(mm Hg)	200	108	291
Mac 3	(mm Hg)	191	104	288
C Mac	(mm Hg)	114	46	198
LMA	(mm Hg)	60	24	102
Trachlight®	(mm Hg)	43	14	72
FOI	(mm Hg)	17	2	34

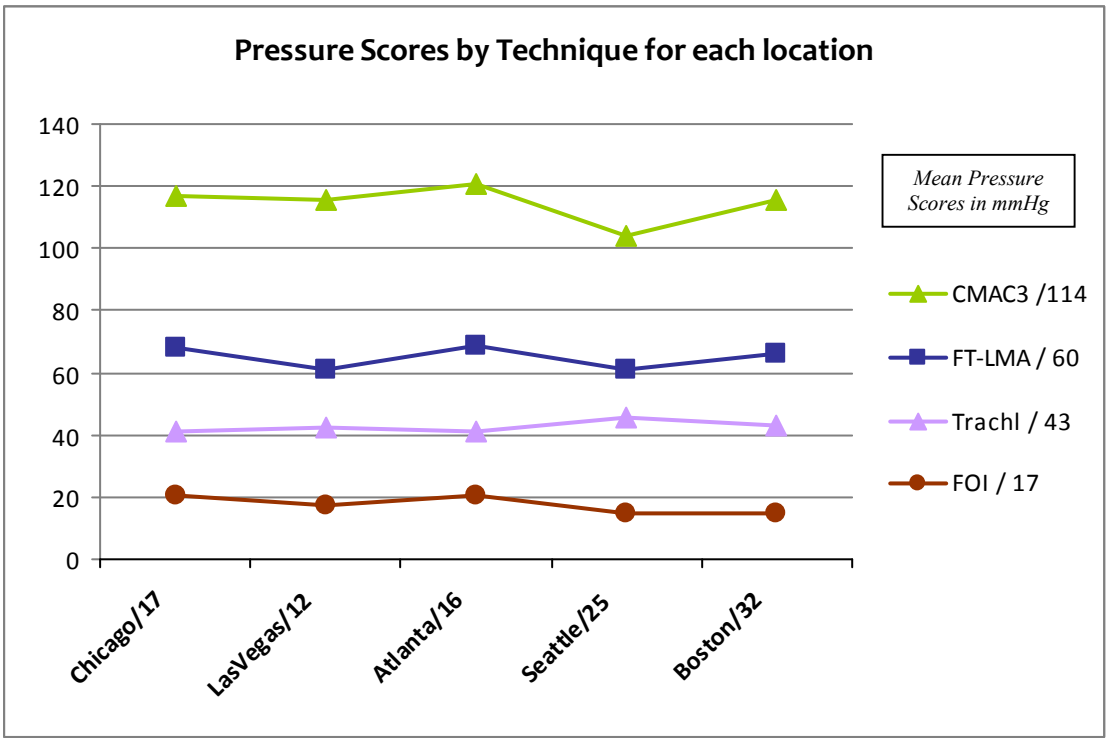


Figure 26. Pressure for Techniques by Locations

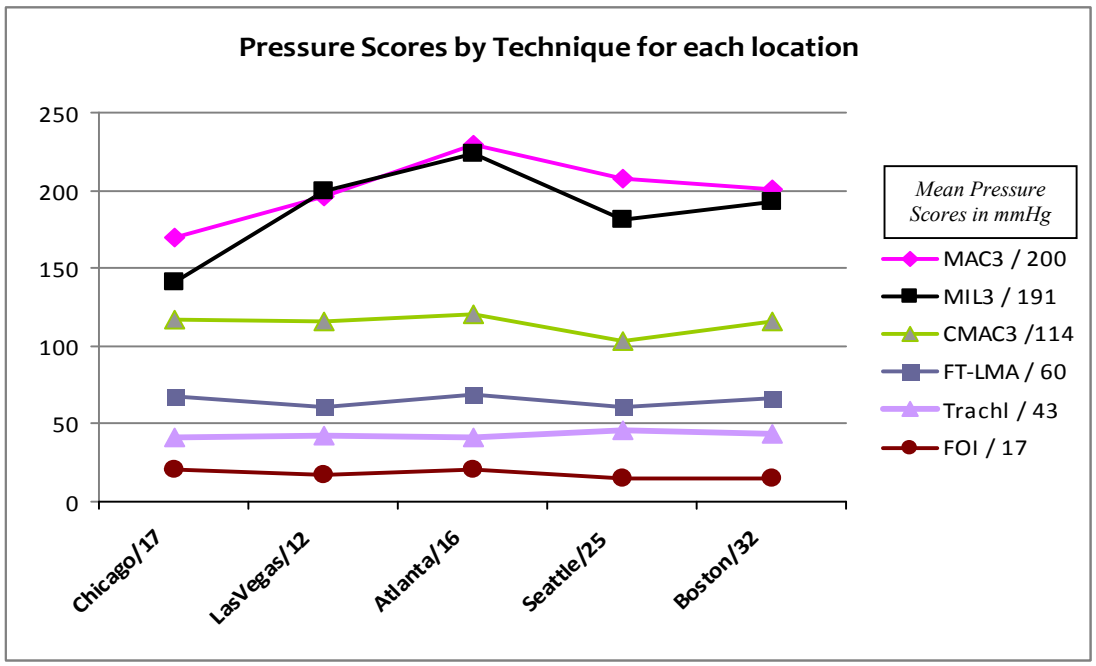


Figure 27. Pressure for Techniques by Location Including Mac 3 and Mil 3 Means

Using the information above, an overall hierarchy of mean pressure can be made. For the purposes of this research, there is an underlying premise that less pressure and therefore less force is a desirable outcome. With this premise in mind, Table 24 is presented.

Table 24. Percent Mean Pressure Reduction

	Mac 3	Mil 3	C-Mac 3	FT-LMA	Trachlight®	FOI
Mac 3	0	\	\	\	\	\
Mil 3	4.50%	0	\	\	\	\
C-Mac 3	43.00%	40.00%	0	\	\	\
FT-LMA	70.00%	68.50%	47.00%	0	\	\
Trachlight®	78.00%	77.40%	62.20%	28.30%	0	\
FOI	91.50%	91.10%	85.00%	71.60%	60.40%	0

\ Indicates an increase in mean pressure

Table 24 demonstrates the percent reduction in pressure associated with each technique. By referring to Table 24, it can be concluded that a reduction of mean pressure by 85% can be achieved by the use of the flexible fiberoptic bronchoscope (FOI) over the use of the C-Mac 3 video laryngoscope. Likewise, a 77.4% reduction in mean pressure can be achieved by the use of the Trachlight® over the use of direct laryngoscopy employing the Miller 3 blade.

It should also be noted that the three techniques found consistently to demonstrate the highest-pressure scores were also those techniques that required the application of a ventral lifting force in order to obtain the required view of the glottic opening. This was similar to the findings made by Wong et al. in 2009 when they compared cervical spinal motions during the use of the Lo-Pro GlideScope®, a commonly used form of video laryngoscope similar to the C-Mac 3, and a flexible fiberoptic bronchoscope. Wong et al. concluded that during the application of even small degrees of ventral lifting force, significant movement of the spine was seen (Wong et al. 2009).

Post–hoc power analysis was assessed using the online free statistical calculator by D. S. Soper, and can be seen in Table 25 (Soper. 2010).

Table 25. Post-Hoc Power Analysis

4 Techniques	
3 Provider Types	N = 102
5 Locations	P = 0.05
Effect Size	Power
Technique 0.811	1.000

Hypothesis 2. This hypothesis stated that there would be a statistically significant difference in mean maximum pressure for each of the three different practitioner types. This hypothesis was not supported by the findings of this research. No difference in pressure scores, as measured by the research mannequin, was demonstrated within the dataset.

Hypothesis 3. This hypothesis stated that there would be no statistically significant difference in mean maximum pressure for each of the five locations of data collection. Support was found for this hypothesis in that no statistically significant difference was found in pressure scores attributable to the location of data collection.

Hypothesis 4. This hypothesis stated that there would be a statistically significant difference in mean maximum pressure for each of the four different techniques by each of the three different practitioner types. This hypothesis was not supported by the findings of this research. No difference in pressure scores attributable to the four different techniques by each of the three different practitioner types was demonstrated.

Hypothesis 5. This hypothesis stated that there would be no statistically significant difference in mean maximum pressure for each of the four different techniques by each of the five locations of data collection. No difference in pressure scores attributable to the four different techniques by the five locations was demonstrated. Therefore, this hypothesis is supported by this research.

Hypothesis 6. This hypothesis stated that there would be no statistically significant difference in mean maximum pressure for each of the three different practitioner types by the five locations of data collection. This hypothesis was supported by the findings of this

research. No difference in pressure scores attributable to the three different practitioner types by the five differing locations of data collections was detected within this research.

Hypothesis 7. This hypothesis stated that there would be a statistically significant difference in mean maximum pressure for each of the four different techniques by the three different practitioner types by the five locations of data collection. This hypothesis was not supported by the findings of this research. No difference in pressure scores attributable to the four different techniques by the three different practitioner types by the five differing locations of data collections was detected within this research.

Although not an explicit goal of the study, the incidental finding of a lack of effect by experience of the provider should be noted. No statistically significant effect was found as measured by the pressure recorded by the research mannequin attributable to the experience of the provider, F=0.00 df =1, P=0.984.

Validity

Internal Validity

Threats to internal validity come from issues effecting causality and inference. The goal of experimental research is to be able to attribute changes in the dependent variable to changes in the independent variable. By ruling out other explanations of dependent variation, causal inference can then be said to have validity. Several of the threats to the internal validity of this study are addressed below.

Historical Threats.

In order to minimize any historical threat to this research, data was collected between September 2009 and May 2010. During this nine-month period, no changes

relative to the practice of airway management were observed. Nor was there any known breach in the experimental protocol or the conditions of the mannequin's assessment of pressure over this time.

Maturation.

Maturation was unlikely to be a threat to the validity of this research due to the short interaction time with each subject. It can be stated with confidence that no maturation effect was possible over the approximately 15 minutes of interaction required of each subject.

Repeated Measures.

Repeated testing could present a threat to the internal validity of this research. This could result from the subjects familiarization with the difficulties of intubation associated with the research mannequin. This had the potential to present a confounding factor by way of explanations for variation in pressures during the first intubation attempt and the following intubation attempts. This threat was considered a priori and addressed by randomly assigning the order of the techniques used by each subject. This would allow for any effect presented by repeated measuring to be minimized by dispersing this variation equally over all six techniques randomly.

Confounding Variables.

No confounding variables were identified during this research. Although the presence of confounding variables was not detected and was unlikely to have influenced the outcomes of this research, the very nature of such variables makes it impossible to rule out their presence completely.

Experimenter Bias.

Experimenter bias is the result of the researcher inadvertently affecting the outcome of the research by unconsciously behaving differently concerning some aspect of the experimental conditions. Due to the nature of the data collection and experimental conditions, this study did lack double blinding and was therefore susceptible to experimenter bias. In order to minimize the threat presented by experimenter bias, care was taken by the researcher to act consistently regarding all variables of interest.

Selection Bias.

One of the largest threats to both the internal and external validity for this research is acknowledged to be the nature of the subjects' selection. Selection bias as it applies to the internal validity of the study relates to the lack of pure equality of the subjects within groups and locations. As stated previously, selection of the research subjects was hampered by the lack of availability of research equipment. Therefore, stratification of subjects by provider type was not achieved. Post-hoc evaluation of the make-up of subjects by location was found to be consistent but not perfectly equal within each location and overall for the study. It is felt that this is not a fatal flaw of the study and perhaps represents a greater natural depiction of provider type then what was proposed

Instrumentation.

The final threat to the internal validity of this research potentially comes from the instrument used to gather the data, that being the performance of the research mannequin itself. It would appear that the mannequin performed consistently throughout this study.

This statement is based on the lack of differences detected between the locations of data collection. Differences detected here could have been attributed to the lack of consistent performance of the mannequin over time or could have been due to differences of experimental setup for each of the specific locations. In addition, the lack of finding a difference for the varying types of providers within locations as well as between locations would suggest consistent performance. The lack of finding differences for the above taken with the differences actually found for techniques and the mannequin's ability to discern the presence of a bi-modal population within the fiberoptic intubation technique demonstrated the mannequin's ability to find differences when present. This would suggest the validity of the instrument. Although one could argue that, the lack of finding differences is not a support of the validity of the instrument itself. Only continued use and analysis can determine the validity of the mannequin's performance.

External Validity

Where threats to internal validity come from issues affecting causality and inference, threats to external validity relate to the appropriateness of generalization of the research results. Several of the threats to the external validity have been addressed for their ability to affect internal validity but are discussed below in terms of their external validity.

Sample Population Bias.

As stated elsewhere in the text, one of the largest threats to both the internal and external validity for this research is acknowledgement of subject selection. Sampling bias as it applies to the external validity of the study relates to the study population being one

of self-selection. All subjects of this study were self-selected first by their attendance at the difficult airway course and then based on their willingness to participate in the research. This self-selection within the study could represent a skewed population in that in order to participate in the research, each subject had to choose to seek additional training in difficult airway management by attending the course. This self-selection may render the findings of the study difficult to generalize to the greater population of airway management providers.

Location Bias.

Threats to the external validity of this research are considered minimal. This is due to the inclusion of five differing locations across the United States as well as the ability of each difficult airway course to attract participants in a regional fashion.

Time Threats**.**

In order to minimize any implications associated with a temporal component to this research, data was collected between September 2009 and May 2010. During this nine-month period, no changes relative to the practice of airway management were observed.

Based on the information above, the generalization of the results of this research study can be said to be at least moderate.

Summary

In this research, the construction and eventual testing of a mannequin designed to provide force feedback during tracheal intubation, while simulating the difficulties associated with the management of a spinal-immobilized patient was achieved. The

ability of the mannequin to detect significant differences within variables was demonstrated. The research mannequin detected findings such as the breach in technique for the use of the trachlight®, and the difficulty advancing the ETT during FOI. Also significant were the findings regarding the failure rates of the six airway management techniques. Affirmative findings for differences in pressure relative to the type of intubation techniques were demonstrated by the research mannequin. The absence of affirmative findings regarding the significance of the type of airway provider, the geographical location of data collection, and the interplay of the two are also important.

The research affirms that the mannequin has the potential to provide a level testing platform for the assessment of airway management techniques and devices not allowed previously. This assessment can take place both intra-device, as in the research design used here or inter-device, such as comparison of differing types of super-glottic airways, or differing types of trans-tracheal–illumination devices. This and other conclusions are discussed in Chapter Five.

CHAPTER FIVE

As stated in Chapters One through Four, the main purpose of this research was to develop and assess the reliability and validity of an experimental model. Thereby providing a means to fill the gaps in the literature that relate to mechanical forces experienced by the patient during interventional airway management. From this incomplete knowledge, clinicians are called upon to make evidence driven decisions on which to base their practice. The foundation of this research was the creation of a means of quantifying the amount of force experienced by a patient during airway management. By creating a mannequin that serves as the measuring tool, the ability to quantify and allow for reproducible cross comparisons of devices as well as other variables was realized.

A review of the study objectives, research questions, and how the results reported in Chapter Four relate to the study hypotheses are reaffirmed below:

Objectives

1. To develop an intubation model with the means of quantifying the force experienced by a patient undergoing the placement of an endotracheal tube
2. To develop an intubation model that simulates the difficulty commonly encountered in spinal immobilized patients.

3. . To then test the experimental model in varying geographical locations with differing clinical providers using a variety of airway management techniques and in that process, assess the validity and reliability of the model.

Operational Questions

The operational research questions of this study were:

A. Is there a statistically significant difference in maximum pressure required for intubation between:

1. Four different airway techniques.
2. Three different clinical practitioner types.
3. Five different geographical locations.
4. The interactions of the four techniques by the three practitioners.
5. The interactions of the four techniques by the five locations.
6. The interactions of the three practitioners by the five locations.
7. The interactions of the four techniques by the three practitioners by the five locations.

Findings and Interpretations

How the findings reported in Chapter Four apply to the study hypotheses are reaffirmed below:

Hypothesis 1. This hypothesis stated that there would be a statistically significant difference in mean maximum pressure for each of the four different techniques. Hypothesis 1 was supported by the findings of this research. These findings would suggest that 81% of the variance in the pressure experienced by a patient undergoing

intubation could be manipulated simply by the selection of the insertion technique, which would represent the ability to control a major portion of the force. This information is best represented in Chapter Four by Figure 27 and Table 23.

It should be noted that the three techniques found to demonstrate consistently the highest-pressure scores were also those techniques that required the application of ventral lifting force in order to obtain the required view of the glottic opening. These techniques are Mac 3, Mil 3, and the C-Mac 3. This was similar to the findings made by Wong et al. in 2009 when they compared cervical spinal motions during the use of the Lo-Pro GlideScope®, a commonly used form of video laryngoscope similar to the C-Mac 3, and a flexible fiberoptic bronchoscope. Wong et al. concluded that during the application of even small degrees of ventral lifting force, significant movement of the spine was seen (Wong et al. 2009).

Table 23 presents the reduction in pressure associated with the use of each technique when compared to the other techniques. By referring to Table 23, the clinician can obtain clinically relevant information. The clinician can select the technique to be used based on the amount of force associated with that technique. Relative information such as a reduction of mean pressure by 85% can be achieved by the use of the flexible fiberoptic bronchoscope (FOI) over the use of the C-Mac 3 video laryngoscope and may prove to be of major relevance in the clinical realm.

Once the above information is replicated over time, it will provide clinical practitioners with a major tool in their ability to control the amount of force experienced by a patient undergoing the placement of an endotracheal tube. These research methods

and findings provide a means for quantitative evaluation and assessment of airway techniques both now and in to the future.

Hypothesis 2. This hypothesis stated that there would be a statistically significant difference in mean maximum pressure for each of the three different practitioner types. This hypothesis was not supported by the findings of this research. No differences in pressure scores, as measured by the research mannequin, were found relative to the type of airway management provider. This finding would indicate that when patient factors are controlled for the amount of force required to place an endotracheal tube, it becomes relative only to the technique chosen rather then the provider type. This is consistent with the findings of Bucx et al (1995) which evaluated the influence of provider experience and type on forces exerted against the teeth of a mannequin model. This group reported that the level of experience has a significant influence on the duration of laryngoscopy but seemed to have little influence on the forces applied to the tongue and incisors. This finding is also consistent with the published findings of Dulisse, and Cromwell, (2010). Dulisse and Cromwell's work entitled "No Harm Found When Nurse Anesthetists Work Without Supervision By Physicians" demonstrated that no differences in mortality or complication rates are present in the Medicare database for solo MDA versus solo CRNA practices. If a relative pressure difference did exist based on the practitioner type, one would expect this difference to be reflected in the overall mortality and complication rate for both solo practicing provider types. This was not the case found in this research in that all three-provider types performed equally with all six techniques.

Hypothesis 3. This hypothesis stated that there would be no statistically significant difference in mean maximum pressure for each of the five locations of data collection. Support was demonstrated for this hypothesis in that no statistically significant difference was found in pressure scores attributable to the geographical location of data collection. This negative finding is similar to the findings regarding hypothesis 2. Combining the findings for hypotheses 2 and 3, the following statement can be made. When patient factors are standardized and controlled, the amount of force required to intubate the mannequin becomes relative only to the technique chosen and would appear to be irrelevant to the geographical location of data collection or the airway provider type.

Hypotheses 4-7. Based on the findings for hypotheses 2 and 3, provider type and the geographic location of data collection not having an influence on the pressure measurements made by the mannequin, the results for hypotheses 4-7 are confirmatory. The results for hypotheses 4-7 add to the findings of hypotheses H2 and H3 only in that no interaction of the two variables demonstrated a statistically significant difference in the pressure detected by the mannequin.

Hypotheses 8-14. All hypotheses regarding time were disregarded due to the extreme unlikelihood of clinical relevance. Mean times for all six airway devices varied minimally with only 16 seconds separating the means of the fastest device from the slowest. No further evaluation of the time data was made. This decision was based on the realization that even in the presence of a statistical significant finding, no meaningful clinical relevance could be inferred based on such a small variation in time. Although for

this model, it can be stated that the type of technique, the location, and the provider were all clinically irrelevant in terms of time required for endotracheal tube placement.

Assessment of the Mannequin Regarding Reliability and Validity

Reliability

In terms of the reliability of the mannequin, it would appear from the data that the mannequin preformed consistently within each location in terms of the assessment of each device as well as the assessment of each provider type. The data also supports the ability of the mannequin to perform consistently over all five of the data collection locations. This represents the ability of the mannequin to provide a consistent testing platform for testing forces associated with interventional airway management that is reproducible following the setup and dismantlement over both time and location. This would seem to begin to form the bases of a reliable tool for future research. No data generated by this research is contradictory to the reliability of the research mannequin.

Validity

The validity of the mannequin's ability to asses the forces experienced by a patient during interventional airway management was supported by several of the findings of this research. First, the research mannequin was able to detect a significant difference in the forces imparted by the use of each of the six techniques. In addition, the forces detected for similar devices such as direct laryngoscopy, using both the Miller 3 and the Macintosh 3 blades were consistently similar in terms of force.

The mannequin was also able to discern a subpopulation within the technique of flexible fiberoptic intubation. This subpopulation consisted of a group experiencing

increased force associated when difficulty of advancement of the ETT over the fiberoptic scope was noticed. Next, within the technique Trachlight®, the mannequin was able to detect the increased force associated with the failure to withdraw the stylet prior to the insertion of the ETT. These finding supports the ability of the mannequin to detect similarities within the types of techniques used as well as differences among techniques. This speaks directly to the validity of the mannequin.

Other Findings and Their Implications of this Research

As stated previously, phase one of this research was undertaken in part to compare the research model against an unaltered Laerdal Mannequin. This comparison measured its ability to simulate the airway management of a patient with a compromising cervical spinal injury. The ability of the research mannequin to do so would appear to be supported by the data generated during the first phase of this study. Additionally phase one had the purpose of piloting the performance of the mannequin in a research setting. Also noted in phase one is the complete agreement between subjects and observers that the research mannequin required more force and was therefore more difficult to intubate. This is consistent with the knowledge that the application of spinal immobilization is known to make the visualization of the glottic opening more difficult. Hence, it requires more force when using a method such as a Macintosh 3 blade that relies on obtaining visualization of the glottic opening (Nolan, & Wilson, 1993. Hastings & Wood, 1994. Heath 1994). This would further indicate that the first modification made to the mannequin's construction consisting of two steel bracings capable of stabilizing the neck, head and torso of the mannequin as a single rigid unit, did in fact simulate the application

of spinal immobilization making the research mannequin more difficult to intubate. No difference between the unaltered mannequin and the research mannequin other than the degree of difficulty to intubate was noted by the subjects or the observer.

For all techniques and users, the maximum pressure found among the three sensing locations was the tongue, followed by the vallecula, and finally the force applied between the head and the headboard. This is supported in that force exerted in a downwards vector is rarely, if ever, a component of intubation. When considering the other two pressure sensing locations within the mannequin, a statement such as the force applied in the area of the vallecula would be less than the force applied more broadly to the tongue, seemed to be a responsible one. This statement is consistent with the findings of this study and seemed to lend some small degree of face validity to the research mannequin. This finding was consistent for all intubation attempts made by all providers.

Major Limitations

The first and most obvious limitation of this study lies in the fact that this is a mannequin study. It should be acknowledged that little in the way of confirmation of the ability to transfer the results of this study to a clinical population is presented. It should also be acknowledged that it was not the intention of this research to do so. Therefore, the assumption of the transferability of this data is believed to be a responsible assumption based on the past use of the standard Laerdal Airway Trainer Mannequin but is subject to be refuted.

The next limitation that should be acknowledged for this research relates to the number of subjects with complete pressure data for analysis. When all six techniques are

considered for analysis using a single statistical model, a reduction of N from 102 cases down to 62 cases occurred. Although this reduction of N is the result of failed intubation attempts attributable to two of the six techniques, it is recognized as a significant finding in and of itself. This reduction of N could greatly increase the risk of a type-two error and was therefore, the impetus for dealing separately with those two techniques that had a high rate of failure.

The third source of limitation was the use of mean substitution. This concern was based on the ability of the technique to alter the relationship among variables when a relatively large percentage of substitutions were made (Tabachnick, & Fidell, 2007). It was for this reason that the variables Mac 3 and Mil 3 were removed from the final analysis rather than employing the method of mean substitution. Although, employing the method of mean substitution did allow for the inclusion of the outliers effect on the mean to be retained in the final analysis. The resulting dataset minimized the effects of outliers but also retained the overall essence of the study.

The final limitation acknowledged for this research was the potential bias of the researcher. This research was conducted exclusively by a single individual and although this reduces inter-observer variation, it elevates the possibility and any effect of a bias. While a concerted attempt to achieve a state of equipoise was made, it is acknowledged that some unconscious behavior concerning an unrecognized aspect of the experimental conditions was a possibility.

Suggestions for Further Research

The high rate of failure for both the three Miller and the three Macintosh blades represents a fertile subject for future investigation using the research mannequin. A failed versus non-failed dummy variable could be created for the Macintosh and Miller techniques. Using a similar multivariate profile analysis for the dependent variable of successful intubation of the two standard laryngoscopy techniques and the interactions with other variables could prove of interest.

Secondly, it was not the intention of this study to incorporate the pressure data obtained from all three pressure-sensing locations within the mannequin in a unified assessment. The presence of this data would pose the additional question of whether the incorporation of this information would allow a greater ability to refine the overall comparisons of pressure patterns for each technique. Secondly, the pressure profiles within the categories of the differing techniques should prove to be a fertile topic for future investigation. This line of research would allow for the exploration of pressure variations specific to the differing devices within categories such as super-glottic airways or trans-tracheal illumination devices. Lastly, the model was designed to simulate the difficulties of intubating a spinal immobilized patient. The presence of difficulty was demonstrated in this research. As suggested by Kihara and colleagues (Kihara, Yaguchi, Taguchi, Brimacombe & Watanabe 2005), the use of spinal immobilization to simulate the management of difficult airway situations during intubation was realized. By applying this to the mannequin, the simulation of the difficult intubation scenario can be standardized and easily replicated.

Regardless of the mechanism of difficulties presented in the model, in this case spinal immobilization, the model's difficulty could be put to other use. This may allow for its use as a tool in assessing and teaching techniques designed to assist in the management of the failed and difficult airway. The nature of the real-time, quantitative feedback may prove invaluable in the future training of healthcare students, as well as the on going, continuing education of licensed providers. It is suggested that these types of questions would be a natural progression for future research. It can be stated that the continued use of the research mannequin in any future research will allow for the on-going evaluation of its validity and reliability.

Summary and Conclusion

The significance of this research lies in its applicability to the type of airway management that occurs each day, throughout the world, in thousands of hospitals providing care to the critically injured. This quantitative study explored a novel and systematic line of research that marshaled quantitative assessment techniques in determining the physical forces that can occur throughout the airway of patients during endotracheal intubation. Using a mannequin that employs transducers situated in anatomically significant locations, this research helps to determine how provider type, experience, and instrument selection influences the pressure on airway anatomy during simulated difficult laryngoscopy.

This research presents a novel approach that can help to provide a better understanding of laryngoscopy and the interplay of spinal immobilization, technique, provider type, and it may have major safety implications.

Chapter Five concludes this research study. It can be stated with confidence that the study did meet its three stated objectives. This study did in fact develop and test an intubation model that quantified forces while simulating the intubation difficulties commonly encountered in the spinal-immobilized patient. It then went on to test the model as intended and reported the results.

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VITA

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